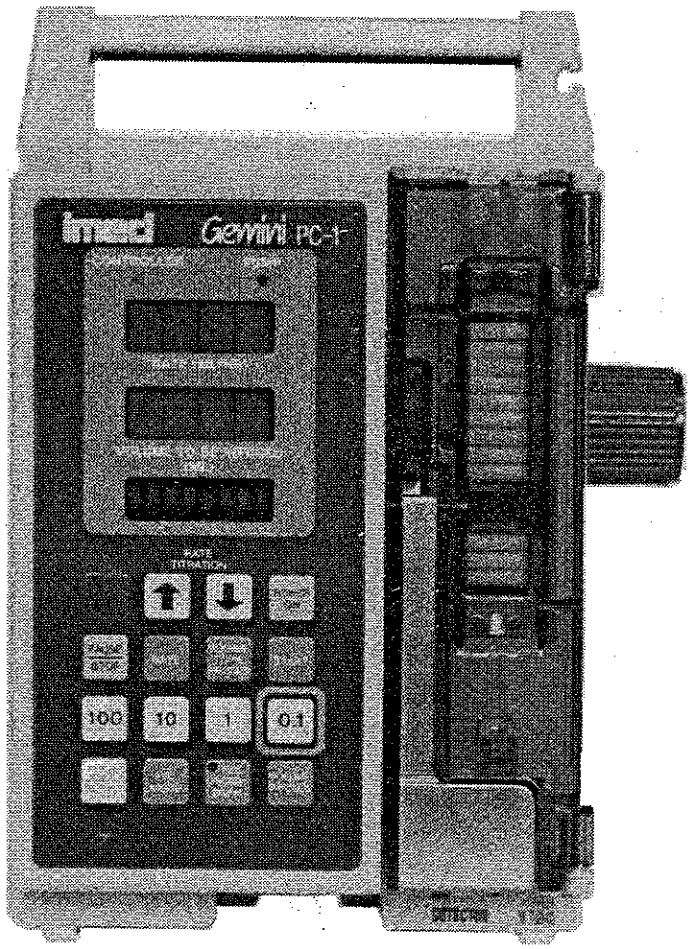
ALARIS®
MEDICAL SYSTEMS

110V and **220V**



imed® Gemini PC-1®

VOLUMETRIC INFUSION PUMP/CONTROLLER

MAINTENANCE MANUAL

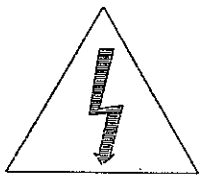
WARNINGS, CAUTIONS AND NOTICES

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

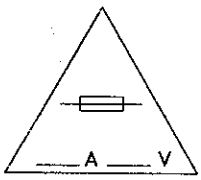
USE ONLY HOSPITAL GRADE POWER SUPPLY CORD TO INSURE PROPER GROUNDING. GROUNDING RELIABILITY CAN ONLY BE ACHIEVED BY CONNECTION TO A RECEPTACLE MARKED "HOSPITAL GRADE".

DANGER: EXPLOSION HAZARD, DO NOT USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

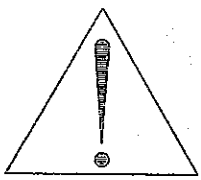
WARNING: TO PREVENT UNRESTRICTED FLOW, CLOSE CLAMP WHEN FLO-STOP IS OPEN.



CAUTION: TO REDUCE RISK OF ELECTRICAL SHOCK, DO NOT REMOVE COVER OR BACK. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.



WARNING: REPLACE FUSE AS MARKED.



CAUTION: BEFORE CONNECTING "REFER TO MANUAL"

NOTE

TO MAXIMIZE THE SERVICE LIFE OF THE INSTALLED BATTERY, IT IS RECOMMENDED THAT THIS INSTRUMENT BE STORED AND OPERATED IN AN ENVIRONMENT THAT IS TEMPERATURE CONTROLLED BETWEEN 68°F (20°C) AND 77°F (25°C).

WARNING

IN THE EVENT THE INSTRUMENT IS DROPPED AT ANY TIME, IT MUST BE CHECKED BY A BIOMEDICAL TECHNICIAN PRIOR TO USE FOR PATIENT CARE.

WARNING AND CAUTION NOTICES

220V

WARNING: TO PREVENT UNRESTRICTED FLOW, CLOSE ROLLER CLAMP WHEN FLO-STOP® MECHANISM IS OPEN.

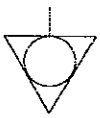
CAUTION: REFER TO MANUAL

CLASS 1

TYPE CF (Equipment useable for direct cardiac applications)

ALTERNATING CURRENT

REPLACE FUSE ONLY WITH SAME TYPE AND RATING



EQUIPOTENTIAL GROUND POINT: IF THE INTEGRITY OF THE EQUIPOTENTIAL EARTH CONNECTION OR HOSPITAL EARTH SYSTEM IS IN QUESTION, OPERATE THE INSTRUMENT USING INTERNAL BATTERY POWER.

IPX1 **DRIP PROOF**

WARNING

If the PC-1 pump/controller is dropped at any time, have the instrument checked by the Biomedical Department prior to further use.

CAUTION

ONLY equipment that has been qualified to IEC 601-1 standards should be connected to the PC-1 pump/controller's RS-232-C Data Port and the connection should ONLY be performed by qualified personnel.

CAUTION

Only systems that have been qualified to IEC 601-1 standards should be connected to the PC-1 pump/controller's Nurse Call connector and the connection should ONLY be performed by qualified personnel.

NOTICE

Product design and/or specifications are subject to change without notice. The information contained in this manual is current as of the date of issue.

This publication contains ALARIS Medical Systems,™ Inc. ("ALARIS Medical") proprietary data provided solely for the use of technical personnel in repairing ALARIS Medical infusion pump/controllers.

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U.S. Patents 4,617,014; 4,689,043; 4,690,673; 4,725,205; 4,728,265; 4,836,752; 4,909,710; 4,920,336; 4,954,046; 4,859,927; 5,219,330; D305,151; D308,946; D312,879. AU 646,216; 580,184; 586,594; 590,179; 601,664; 607,112; 622,088; 604,477. CA 1,235,033; 1,258,212; 1,300,977; 1,280,647; 1,296,791; 2,020,926; 1,238,832. AT 0,225,158. BE 0,225,158. FR 0,225,158; 283,614; 315,312; 0,431,726; 0,238,277. GB 0,225,158; 283,614; 315,312; 0,431,726; 0,238,277. NL 0,225,158; 283,614. IT 0,225,158; 283,614. SE 0,225,158; 283,614. CH 0,225,158. DE P3686558.3; P3772,556.9; 3871721T2; P6908208; P3774598. TW UM52721. JP 特許第１７５４４７０号; 特許第１８１６８７２号; 特許第１９０２３８７号; 特許第１９６７１６８号; 特許第１７９３１１９号; 特許第１７３０３９５号.

Other US and Foreign Patents Issued and Pending.
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PREFACE

This manual contains operation and maintenance instructions for the IMED® GEMINI PC-1® Volumetric Infusion Pump/Controller ("PC-1"). The information provided herein is intended for use by technical personnel responsible for servicing this product. The material is divided into six sections and is presented as follows: Section 1 - Descriptive Information; Section 2 - Preparation for Use; Section 3 - Operating Instructions; Section 4 - Functional Description and Schematic Diagrams; Section 5 - Maintenance Instructions; Section 6 - Parts Lists and Assembly Drawings; Section 7 - Calibration and Preventive Maintenance.

Additional copies of this manual may be obtained by contacting ALARIS Medical's Customer Service Department.

This manual supersedes PC-1 Maintenance Manuals 1310-9251-00 and 1310-9261-00 and 1310-9261-00 and PC-1 International Addendum P/N 1310-9028-00.

The features of the 220V model of the PC-1 pump/controller have been incorporated into this manual. Text or graphics that are related exclusively to the 220V model are identified with a 220V symbol.

In addition, some features are for the 110V model of the PC-1 pump/controller only and are identified with a 110V symbol.

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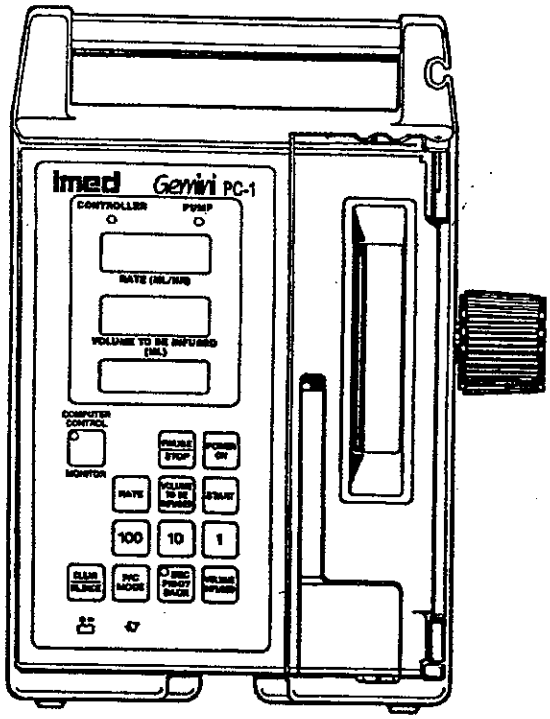
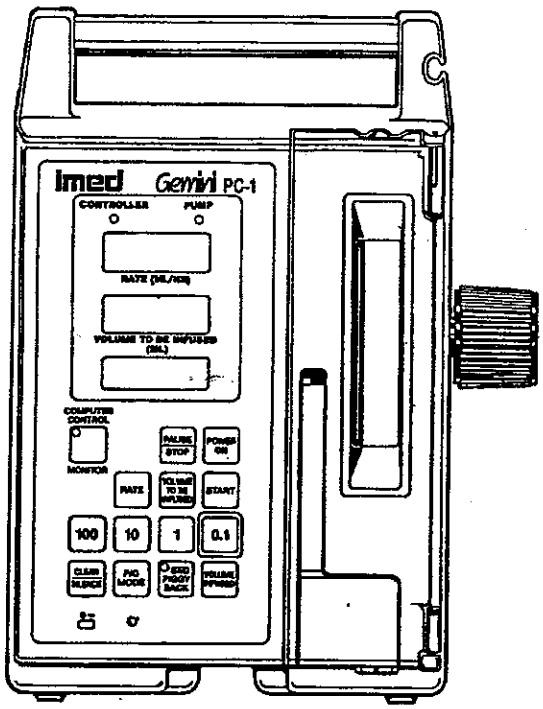
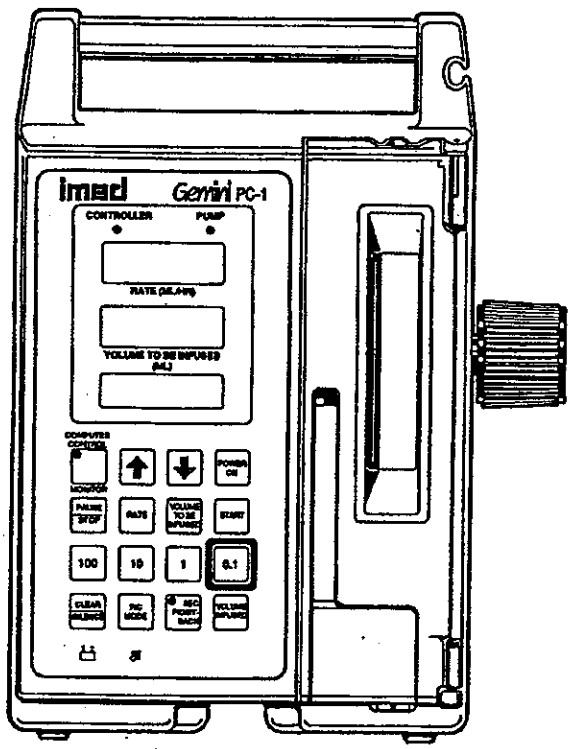


Integer Keypad



Fractional Keypad



Titration Keypad

Figure 1-1 IMED® GEMINI PC-1® Volumetric Infusion Pump/Controller

SECTION 1 - DESCRIPTION

1.1 INTRODUCTION

This section includes general operating characteristics, physical description and operating specifications for the IMED® GEMINI PC-1® Volumetric Infusion Pump/Controller ("PC-1").

1.2 OPERATING CHARACTERISTICS

The PC-1 instrument is a single channel volumetric infusion pump/controller used for the administration of intravenous drugs and fluids. The instrument can be operated as either a Pump or Controller. A lockout feature is incorporated which allows the instrument to be preset as either a Pump or Controller. Secondary (piggyback) infusions can be administered using infusion parameters independent of the Primary infusion. An Empty Container Detector (ECD) is available, as an option (All except PC-1CE v8.xx 220V), to permit infusing the entire contents of an IV solution container. The instrument is compatible with remote computer operation when the communication option is installed. An integral maintenance mode is incorporated to monitor instrument performance, identify and document instrument malfunctions and assist technical personnel in troubleshooting and repair.

Fractional Keypad/Series V5.xx & Subsequent Software
A VersaTaper® Mode is incorporated to facilitate administration of IV fluids that require non-linear delivery (rate and/or VTBI) during the period of medication. Twenty, manually input, independent steps (rate and VTBI combinations) are available to set up a tapered infusion program.

Titration Keypad/Series V7.xx & Sub. Software
An AutoTaper® Mode is incorporated to automate infusion setup and delivery of ramp-up/taper-down cyclic parenteral nutrition applications.

The PC-1 pumping mechanism employs linear peristaltic action to deliver a continuous flow of infusion products reliably, accurately and safely. In the controller mode, the instrument will deliver fluid at a pressure equal to the pressure created by the head height of the IV solution container ±12 inches (30 cm). In the pump mode, the instrument delivers fluid at a pressure up to a maximum of 10 ±2 psi (69 ±14 kPa; 517 ±103 mmHg). Above these pressures, the instrument will occlude.

Integer Keypad/Series V2.xx Software
Infusion rate is selectable between 1 and 999 mL/hr in 1 mL/hr increments. Volume to be infused (VTBI) is selectable between 1 and 9999 mL in 1 mL increments. When an infusion is complete, the instrument automatically switches to the KVO rate of 1 mL/hr.

Fractional Keypad/Series V5.xx & Sub. Software
Infusion rate and VTBI are dependent on the selected instrument operating mode - Micro, Macro or Universal. Available parameters are as follows:

MICRO (mic) - Rate is selectable between 0.1 and 99.9 mL/hr in 0.1 mL/hr increments; VTBI is selectable between 0.1 and 999.9 mL in 0.1 mL increments.

MACRO (mac) - Rate is selectable between 1 and 999 mL/hr in 1 mL/hr increments; VTBI is selectable between 1 and 9999 mL in 1 mL increments.

UNIVERSAL (mic/mac) - Rate is selectable in 0.1 mL/hr increments between 0.1 and 99.9 and in 1 ml/hr increments between 100 and 999 mL/hr; VTBI is selectable in 0.1 mL increments between 0.1 and 999.9, when the Rate is fractional, and otherwise in 1 mL increments between 1 and 9999 mL.

When an infusion is complete, the instrument automatically switches to a KVO rate of 1 mL/hr for delivery rates ≥1 mL/hr or a rate equal to the set delivery rate for rates <1.0 mL/hr.

This version of the PC-1 pump/controller incorporates a feature that allows the instrument to be preset in either the Micro (mic), Macro (mac) or Universal (mic/mac) mode.

Rate Titration Keypad/Series v7.xx
The Rate Titration feature allows the rate to be increased or decreased 1 mL/hr (MACRO mode) or 0.01 mL/hr (MICRO mode) with each press of the ⇩ or ⇧ control, then press START to accept the new rate. Greater rate changes can be achieved by pressing and holding the appropriate ⇩ ⇧ controls until the desired rate is obtained, then press START to accept the new rate.

The PC-1 pump/controller does not require any pre-operational warm up. An internally mounted battery provides normal operation for a limited period to enable use when AC power is not available or the external power source is interrupted.

The PC-1 pump/controller's user interface consists of a front panel tactile keypad and the rear panel Audio Control potentiometer. Tamper resistant operation is provided through the requirement to utilize a prescribed key press sequence to enter or change infusion parameters. Basic operating instructions are printed on the right side of the instrument case. Functional control is provided by a 16 bit microprocessor using a stored program that includes a diagnostic routine that monitors pump performance, provides audio and visual signals to ensure proper sequencing of normal operations and initiates an alarm in the event a software or hardware malfunction is detected.

Sufficient disposable configurations are available to provide the user with a full range of set-up combinations (see Section 1.7). The Flo-Stop® on the GEMINI administration set's pumping segment prevents free flow in the event the tubing set is removed from the instrument following initial installation. Free flow, as a result of deliberate operator action, is possible when using the set to perform a gravity infusion in accordance with the instructions provided in the set package.

1.3 OPERATING CONDITION

The PC-1 pump/controller can be operated independently (Normal Operation) or, when configured with a communication data port, as a computer controlled device (Computer Operation). Normal operation includes the Controller and Pump modes plus the Maintenance mode. Computer operation includes the Monitor and Computer Control modes.

NORMAL OPERATION

SETUP MODE **V7.xx and subsequent software**

The Titration keypad instruments utilize the Setup Mode (refer to Section 2.3.3.2) to configure the instrument for specific infusion regimes, language selection and communication (serial port) parameters.

CONTROLLER MODE

In the CONTROLLER mode, the PC-1 pump/controller is programmed to control the infusion of a specific volume of IV solution. The instrument senses and responds to container height and patient-side pressure in a manner similar to a gravity infusion. The instrument's pressure sensor measures the hydrostatic pressure from the fluid container and compares that pressure against distal tubing in-line pressure. When in-line pressure exceeds pump input pressure, an occlusion condition exists and an alarm is initiated. Actual delivery pressure is directly proportional to container height; increasing container height raises and decreasing the height reduces occlusion pressure. Controller mode occlusion pressure tolerance is ±12 inches (30.54 cm) from the fluid container height. Transient surges in patient-side pressure above the occlusion threshold of <60 seconds duration will produce a LOW FLOW condition which stops the infusion while the pressure is above the occlusion threshold. Pressure transients above the occlusion threshold for periods longer than 60 seconds duration or cumulative time required to compensate for volumetric deficiency in excess of 30 minutes will initiate an occlusion alarm.

PUMP MODE

In the PUMP mode of operation, the instrument employs a preset occlusion pressure limit of 10 ±2 psi (69 ±14 kPa; 517 ±103 mmHg) predicated on a nominal container height of 24 inches (61 cm) and a delivery rate >30 mL/hr. For delivery rates <30 mL/hr, the occlusion pressure is rate-dependent to ensure timely detection of occlusion conditions. Any transient distal in-line pressure above this limit will generate a patient-side occlusion alarm.

Software Release V6.xx and Subsequent
These instruments can be locked into a rate-independent (10 psi) occlusion pressure mode. This mode will result in significantly increased time-to-occlusion for rates <30 mL/hr.

Software Release v8.13 only
These instruments can be locked into a rate-independent (517 mmHg) occlusion pressure mode. This mode will result in significantly increased time-to-occlusion for rates <30 mL/hr.

MAINTENANCE/DIAGNOSTIC MODE

Integer/Fractional Keypad Instruments
The Maintenance mode is intended solely for use by biomedical technicians to perform servicing and maintenance actions and must **NEVER** be used when the PC-1 pump/controller is connected to a patient. The maintenance mode provides biomedical service personnel access to the closed loop diagnostic test routines and allows the pumping mechanism to be operated unencumbered by stoppages resulting from alarm and malfunction conditions. Specific sub-routines are incorporated in the maintenance test sequence to permit configuring the instrument for non-English language and computer operation (see Section 5.3 for detailed operation).

Titration Keypad Instruments
The Diagnostic mode provides biomedical service personnel access to the closed loop diagnostic routines, allows the pumping mechanism to be operated uninterrupted by stoppages resulting from alarm conditions and maintains a log of the 24 most recent error codes (see Section 5.3 for detailed operation).

COMPUTER OPERATION
Fractional/Titration Keypads with Software Release V6.xx and Subsequent ONLY

MONITOR MODE

The Monitor mode allows a host computer to monitor infusion status and instrument performance. Monitor mode is enabled when a host computer is connected to the PC-1 pump/controller through the Communications Data Port (RS-232-C) and the Monitor indicator is illuminated.

COMPUTER CONTROL

The Computer Control mode allows an infusion, once set up, to be controlled and monitored by a host computer installation. Computer controlled operation is selected by actuating the COMPUTER CONTROL/MONITOR switch after Monitor mode has been established. Computer controlled operation is confirmed by the computer control indicator presentation changing from flashing to a steady illumination.

1.4 USER INTERFACE

The front Control and Display panel incorporates a tactile keypad for operator use in programming an infusion. Delivery mode (if not locked), Rate and Volume to be Infused are each selected for Primary infusions. A SEC/PIGGYBACK (Secondary) key permits independent selection of Rate and VTBI for a sequential secondary infusion. Separate registers are provided to accumulate Total and Secondary volume infused quantities. The PAUSE/STOP control allows an infusion to be "paused" and then resumed or stopped. Rate and VTBI infusion parameters for the Primary or Secondary are displayed digitally in the respective displays. The operator information display presents visual prompts, advisories, alarms and/or malfunctions messages as appropriate to assist the operation in programming and operating the instrument.

Fractional Keypad/Series V5.xx & Sub. Software
The 0.1, 10, 100, VTBI, VI, PC and CLEAR/SILENCE keys have a secondary function during instrument power up to enable or clear

discrete delivery mode selections available on these versions of the PC-1 pump/controller.

Titration Keypad/Series V7.xx & Sub. Software
The keypad adds the rate titration controls ⌂ and ⌂ which enable the user to quickly increase or decrease the rate parameter. A tamper resistance feature is enabled in the SETUP mode and implemented using the push actuation of the Audio/ Tamper Resistance Control on the rear panel.

The requirement to properly install the administration set's integral Flo-Stop before the door will close and latch prevents inadvertent "free flow," inhibits premature operation of the pump and prohibits use of an unauthorized set. The Door Open and Air-in-Line sensors are provided to stop pump operation if either of these conditions occur during an infusion. A strain relief fitting is provided in the instrument's handle support to prevent kinking of the proximal tubing.

The rear panel of the PC-1 pump/controller is configured with an audio volume control and an ECD connection (ECD connection - All except PC-1CE v8.xx 220V). A RS-232-C data port connector is incorporated on the power supply board for the Fractional Keypad instruments. Software releases V6.xx and subsequent enable the PC-1 pump/controller for computer controlled operation.

IMED® GEMINI Series disposable administration sets are required for use with the GEMINI family of Infusion Pump/Controllers. Sufficient set types are available to support a broad range of infusion types and configurations.

1.5 PHYSICAL DESCRIPTION

The PC-1 instrument has the following physical characteristics:

Height: 10.8 inches (27.5 cm)
Width: 8.4 inches (21.3 cm) w/pole clamp
Depth: 6.5 inches (16.5 cm) w/pole clamp
Weight: 11.1 pounds (5.1 kg)

The PC-1 instrument consists of two major assemblies: the front and rear case.

FRONT CASE

The front case assembly consists of a high-impact, injection molded, plastic case/insert assembly with an Electro-Static Discharge (ESD) coating, which houses and supports the pumping chamber access door, the peristaltic pumping mechanism, pressure transducer (strain beam), Air-in-line and slide clamp detectors, the multi-card assembly, keypad and front case ESD components.

REAR CASE

The rear case assembly consists of a die-cast aluminum shell which mounts and supports internally the battery, transformer, power supply board (with sonalert), ECD connector (except PC-1CE v8.xx 220V), audio control potentiometer and RS-232-C connector) and power entry module. The exterior of the rear case supports the pole clamp, ECD storage fitting, power cord retention strap and power cord retainer.

220V **only.** The exterior of the rear case supports the 220V AC power entry module plus the equipotentiality grounding point. The power entry module includes fuses for both input leads and a 220V AC power interrupt switch (where applicable).

1.6 PRODUCT HISTORY

The initial release of the Gemini PC-1® Infusion Pump/Controller was in October 1988. Since that time a number of changes have occurred. The initial release PC-1 is an "Integer" Infusion Pump/ Controller, it delivers fluids in whole number increments only. The next iteration of PC-1 delivered fluid in whole and fractional increments and incorporated "VersaTaper®" an intravenous feeding algorithm. Then the PC-1 was updated to interface with the RS-232 bus. The last major change incorporated "Rate Titration" keys which allows the user to increase/decrease the rate by small increments with a minimum number of key presses. This model also incorporated AutoTaper® which is a predefined intravenous feeding algorithm. These instruments can be identified by their keypads, The Keypad without a fractional key is the "Integer" model. The Keypad with a fractional key is the "Fractional" model. The Keypad with ↑ ↓ keys is the "Titration/Fractional" model. Refer to Table 1-1 for product history.

1.7 OPERATING SPECIFICATIONS

The PC-1 Operating Specifications are subordinated into Operating Requirements and Performance Specifications which are delineated in Tables 1-2 and 1-3, respectively.

1.8 ACCESSORIES

The accessories approved for use with the PC-1 pump/controller are listed in Table 1-4.

Table 1-1. Product History

Model	History
Integer PC-1	• Initial release of product Software version 2.xx.
Fractional PC-1	• Fractional rate, VersaTaper® introduced Software version 5.xx.
Fractional PC-1	• RS-232 interface enhanced 10psi mode introduced. Software version 6.xx.
Titration/Fractional	• Rate Titration, Tamper mode and AutoTaper® introduced. This unit has a Configuration Setup Mode that can be accessed by holding the "Volume Infused" key at Power Up. Software version 7.xx.
International PC-1	• This unit was developed to meet international requirements. Software version 8.xx.

Revision Matrix:

Revision #	PC-1 2.xx	PC-1 5.xx	PC-1 6.xx	PC-1 7.xx	PC-1 8.xx
A	X	X	X	X	X
B					X
C					X
D		X	X		
E					
F	X				

Revision "A" - Initial Revision
Revision "B" - Software Upgrade for International Units to enhance operation.
Revision "C" - Software Upgrade to change "PSI" to "mm/hg".
Revision "D" - Mandatory Upgrade to incorporate "Crowbar" circuit for 2.xx units. This circuit will cause the line fuse to blow if the battery is in an overcharge condition.
Revision "E" - Not used.
Revision "F" - Mandatory Upgrade to incorporate "Crowbar" circuit for 5.xx and 6.xx units. This circuit will cause the line fuse to blow if the battery is in an overcharge condition.

Note[1]: xx = a number associated with a particular software version, i.e., 2.xx could be 2.09 or 2.13 or 2.16 etc.

Note[2]: All PC-1's have a Maintenance or Diagnostic Mode. To access this mode: hold in the Computer key at Power Up; press the "Computer" button to step through; press the "Start" button to access each function..

CAUTION: The "Fractional" and "Integer" Pumping Mechanisms are not interchangeable.

Table 1-2. Operating Requirements

Parameter	Specification
Power Required:	**Non-Dual State Charger Instruments** 90-132 VAC, current draw 0.2 Amps maximum (25 watts), 0.1 Amps nominal (12 watts), fused at 0.4A, 50-60 Hz, 3 wire, Single ϕ **Dual State Charger Instruments** 90-132 VAC, current draw 0.3 Amps maximum (35 watts), 0.1 Amps nominal (12 watts), fused at 0.5A, 50-60 Hz, 3 wire single ϕ 220V 180-264V AC 0.15 Amps nominal, Fused at 0.315 A, 50-60 Hz, 3 wire, Single ϕ
Battery:	Sealed Lead-acid, 6 VDC, 7.2 Amp-Hr
Operating Temperature Range:	40°F (5°C) to 104°F (40°C)
Operating Humidity Range:	0% to 95% Relative Humidity, non-condensing
Storage/Transport Temperature:	-40°F (-40°C) to 158°F (70°C)
Storage/Transport Humidity:	0% to 95% Relative Humidity, non-condensing

Table 1-3. Performance Specifications

Parameter	Specification
Operating Principle:	Linear Peristaltic
Operating Range:	
Pump and Controller modes:	
Integer Keypad/Series V2.xx Software	
Rate:	1-999 mL/hr in 1 mL/hr increments (**CONTROLLER Mode maximum recommended rate is 500 mL/hr**)
Volume-to-be-Infused:	1-9999 mL or ALL (with external ECD)
Keep Vein Open (KVO) Rate:	1 mL/hr
Fractional/Titration Keypad/Series V5.xx & Subsequent Software	
Rate:	MICRO: 0.1-99.9 mL/hr in 0.1 mL/hr increments MACRO: 1-999 mL/hr in 1 mL/hr increments UNIVERSAL: 0.1-99.9 mL/hr in 0.1 mL/hr increments; 100-999 mL/hr in 1 mL/hr increments (**CONTROLLER Mode maximum recommended rate is 500 mL/hr**)
Volume-to-be-infused:	MICRO: 0.1-999.9 mL in 0.1 mL increments MACRO: 1-9999 mL in 1 mL increments UNIVERSAL: 0.1-999.9 mL in 0.1 mL increments; 1000-9999 mL in 1 mL increments

NOTE

In the Universal mode the Rate parameter determines whether the instrument will operate with fractional or integer values.

When selecting VersaTaper®, the instrument will be configured for either Micro or Macro parameters depending on rate value programmed for Step 01.

Keep Vein Open (KVO) rate: 1 mL/hr if delivery rate is ≥1 mL/hr, or set delivery rate if <1.0 mL/hr.

Occlusion Pressure:

Controller Mode: ±12 inches (30.48 cm) from nominal bottle height

Pump Mode: 10 ±2 psi (69 ±14 kPa;517 ±103 mmHg). At delivery Rates below 30 mL/hr, occlusion pressure is time dependent to ensure rapid response to occlusion conditions.

Software Release V5.59, V6.xx and Subsequent
10 psi mode - occlusion pressure is 10 ±2 psi for all rates.

Software Release v8.13 only
517 mmHg mode - occlusion pressure is 517±103 mmHg for all rates.

Air-In-Line Detection: Dual Mode Ultrasonic (nominal 75µL - single boli; 1 ml within 15 minutes - accumulated air)

Software Release v8.xx
Accumulated air-in-line detection of 1 ml in any 15 min interval.

Secondary (Piggyback): Dual rate programmable

Communications Data Port: EIA Standard RS-232-C. Requires standard 9 pin subminiature D connector

Visual Messages:

PROMPTS: SELECT P/C MODE, PRESS START, SET RATE and SET VTBI

ADVISORIES: PRIMARY, SECONDARY, MAINTENANCE **[V2.XX/5.XX/6.XX]**, DIAGNOSTIC **[V7.XX/V8.XX]**, PAUSE, INFUSION COMPLETE-KVO, LOW FLOW, EMPTY CONTAINER-KVO (All except PC-1CE v8.xx 220V), LOW BATTERY, TOTAL VOL INFUSED and SEC VOL INFUSED

Fractional Keypad/Series V5.xx & Subsequent Software
Additional Advisories: MICRO, MACRO, VERSATAPER: SETUP, STEP:xx, STEPS:xx, TOTAL VOL:xxxx, DURATION:hh:mm, VERSATAPER, and TIME LEFT:hh:mm.

Software Release V6.xx and Subsequent
10 psi

Software Release V6.3x and Subsequent
LOW BATTERY...

Software Release v8.13 only
517 mmHg

ALARMS:	CHECK ECD (All except PC-1CE v8.xx 220V), CHECK IV SET, CLOSE DOOR, AIR IN LINE, OCCLUDED, "FLO-STOP" OPEN / CLOSE DOOR, OCCLUDED-PATIENT SIDE, OCCLUDED-FLUID SIDE, PARTIAL OCCLUSION-FLUID SIDE, KVO COMM CABL, KVO COMM TOUT and KVO, ACCUMULATED AIL (V8.xx)
MALFUNCTIONS:	HELP BATTERY, HELP INTERNAL ERROR and (WATCHDOG)
Delivery Mode/Operating Indicator:	Flashes 500 msec on, 500 msec off when instrument is infusing
Battery Operation:	5 hours to HELP BATTERY condition with a new, fully charged battery and the instrument operating at 125 mL/hr. Battery capacity will diminish over time dependent on usage.

Battery Charging-

Instruments without Dual State Chargers

Instrument - Off:	4 hours will recharge a new battery to battery operation specification level (≈90% capacity)
Instrument operating at 125 mL/hr:	18 hours recharge will restore a new battery to a fully charged condition

NOTE

To maximize battery life, recharge battery for 10 hours with the power off or 24 hours with the power on between consecutive battery operations.

Instruments with Dual State Charger

Instrument Off or Operating at 125 mL/hr:	4 hours will recharge a new battery to battery operation specification level (≈90% capacity)
	10 hours recharge will restore a new battery to a fully charged condition

NOTE

Failure to fully recharge the battery between consecutive battery operations will reduce battery life.

Audio Characteristics:

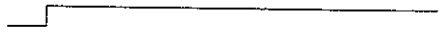
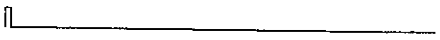
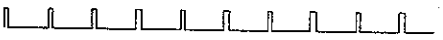
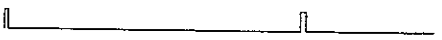
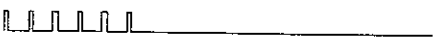
AUDIO TYPE	AUDIO PERIOD	VOLUME VAR/FIXED	SILENCE YES/NO
(1) MALFUNCTION v2.xx/5.xx/6.xx v7.xx	 CONSTANT TONE 600 msec ON, 0.5 sec OFF 600 msec ON, 3 sec OFF	MAXIMUM 75db FIXED	NO
(2) KEY CLICK	 30 msec ON (Once)	VARIABLE	YES
(3) ALARM v2.xx/5.xx/6.xx v7.xx	 600 msec ON, 3 sec OFF 600 msec ON, 1.5 sec OFF	VARIABLE	YES
(4) PROMPT	 100 msec ON, 2 sec OFF	VARIABLE	YES
(5) ADVISORY	 100 msec ON, 15 sec OFF	VARIABLE	YES
(6) CHANGEOVER	 100 msec ON, 400 msec OFF (6 beeps)	VARIABLE	NO (v2.xx) YES (v3.xx)

Figure 1-2. Audio Characteristics

Table 1-4. Accessories

Part No.	Description
1303	Communications Test Plug (optional)
1308	Empty Container Detector (for use with Non-Universal spike sets) (110V and 220V prior to software v8.xx)
20-2370-7	Syringe Holder
3299-100	Calibrated Tubing (optional)

SECTION 2 - PREPARATION FOR USE

2.1 INTRODUCTION

This section contains information relative to the initial inspection and pre-operational checkout of the IMED® GEMINI PC-1® Volumetric Infusion Pump/Controller ("PC-1"). These procedures include a mechanical inspection, electrical inspection, pre-operational battery charge and a performance check to ensure that the instrument operates properly and has not been damaged during shipment or storage. The PC-1 pump/controller's operating features are identified in Figure 2-1.

2.2 PRE-OPERATIONAL MECHANICAL INSPECTION

The PC-1 pump/controller has undergone thorough production control and quality assurance testing prior to shipment from the factory. The shipping container has been designed to protect the instrument against damage under normal shipping conditions; nevertheless, internal physical and/or electronic component damage could have occurred without leaving a visible signature. Therefore, it is recommended that the following inspection procedure be performed upon receipt of the instrument at the user's facility.

1. Carefully remove the PC-1 pump/controller from the shipping container. (It is recommended the shipping material be saved in the event the instrument has been damaged and must be returned to the factory for service or repair).
2. Inspect the exterior case, front and rear, for holes, cracks, scratches, spalling, broken or damaged controls, missing components and/or screws.
3. Inspect the amber and green tinted Lexan® windows covering the indicator displays for scratches or cracks.
4. Ensure the pumping chamber access door fits flush with the case at the top, bottom, and sides.
5. Check the door handle/cam lock for ease of operation and flush fit with door when latched.
6. Inspect the pumping mechanism seal for damage and to ensure they are properly attached to the front case.
7. Inspect the air-in-line sensor and Flo-Stop recess for damage or obstructions.
8. Install an approved IMED GEMINI administration set to ensure the Flo-Stop assembly seats correctly and the door closes and latches properly.
9. Actuate each of the keypad controls on the front panel and the audio volume control potentiometer on the rear panel to ensure proper operation (see Figure 3-1 for location of controls).
10. Inspect the power cord for damage, bent prongs or deformed connector.
11. Exercise the pole clamp mechanism to ensure freedom of movement.
12. 220V **only.** Inspect AC Power Input Module for proper number and type of fuses, and unrestricted operation of the Power Interrupt switch (where applicable) as well as for physical damage and/or missing parts.
13. 220V **only.** Inspect Equipotentiality Ground Point for damage and security.

NOTE

In the event the PC-1 pump/controller shows evidence of shipping damage, notify the carrier's agent immediately. Do not return a damaged instrument to the factory before the carrier's agent has authorized repairs. Contact ALARIS Medical for authorization to return the instrument for repair regardless of liability for repair costs.

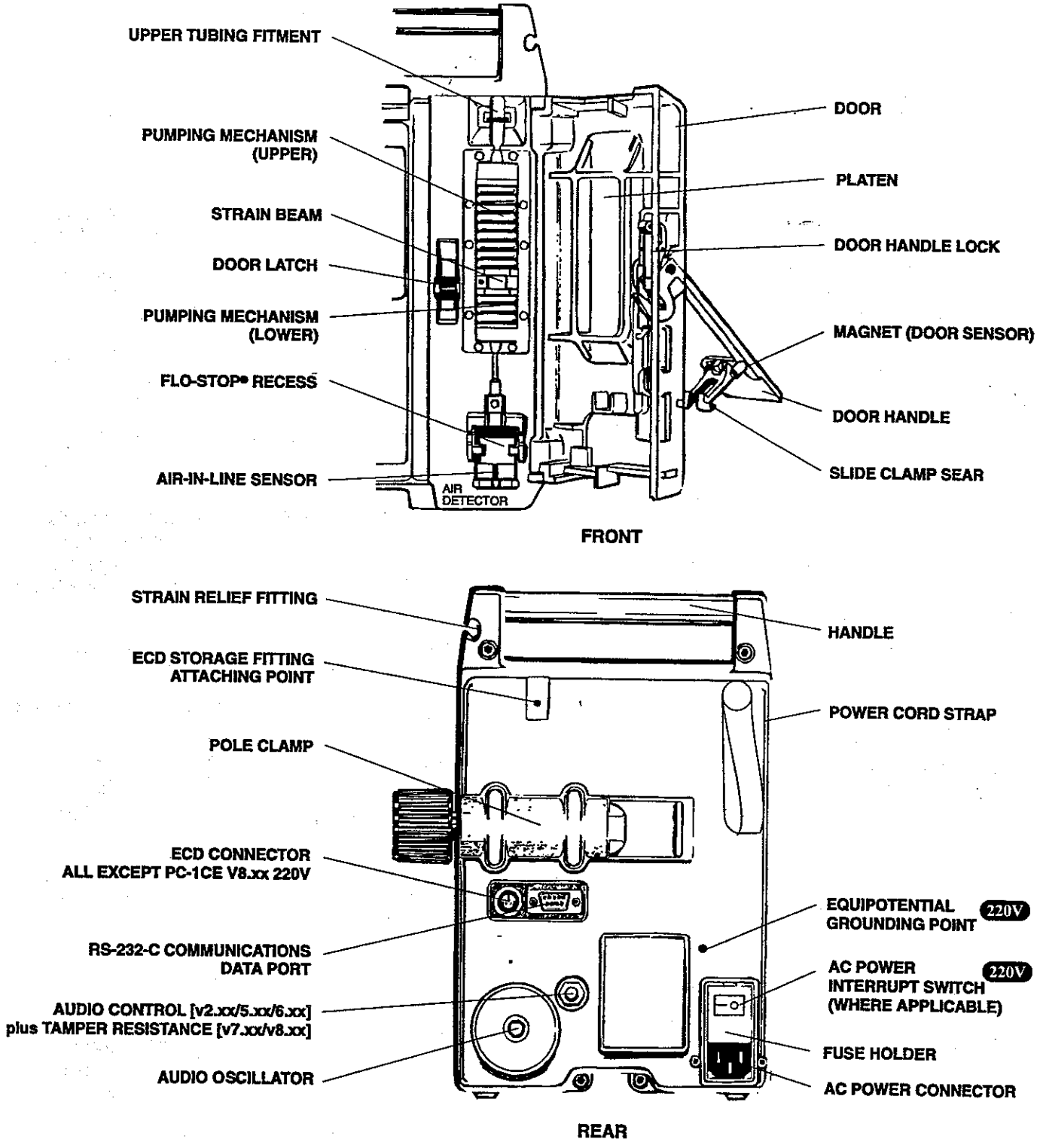


Figure 2-1. PC-1 Front and Rear Operating Features

2.3 OPERATIONAL PERFORMANCE CHECK

Prior to the first operational use and following any routine maintenance or servicing of the PC-1 pump/controller, it is strongly recommended that an operational performance check be performed. The operational performance check consists of two phases; a Pre-operational Electrical Inspection to check the electrical integrity of the instrument for compliance with regulatory agency requirements and an Operational Performance Test to verify proper pump/controller operation.

2.3.1 Pre-operational Check Battery Charge

The battery is fully charged upon completion of the post manufacturing quality assurance inspection. However, since considerable time could elapse between manufacture and first use, a pre-operational battery charge is recommended. Connect the AC power cord to an AC outlet and allow the battery to charge for 24 hours.

2.3.2 Pre-operational Electrical Inspection

The pre-operational electrical inspection includes an electrical leakage test and a ground continuity check.

CAUTION

Some of these tests are inherently hazardous. Safeguards for personnel and property should be employed when conducting such tests. Tests should only be performed by qualified personnel.

2.3.2.1 Electrical Leakage Test

Perform an electrical leakage current measurement in compliance with Underwriters Laboratories (UL) 544 for Patient Care Equipment and/or Canadian Standards Association (CSA) Standard C22.2 No. 125 for Risk Class 2G Equipment. Leakage currents are to be less than 100 microamperes.

2.3.2.2 Electrical Ground Test

Perform an electrical ground impedance measurement in compliance with UL 544 for Patient Care Equipment and/or CSA Standard C22.2 No. 125 for Risk Class 2G Equipment. The impedance between the grounding pin on the power cord plug and the grounding point on the rear case should not exceed 100 milliohms.

2.3.3 Abbreviated Operational Performance Test

The following operational performance test is designed to ensure each of the PC-1 pump/controller's controls and indicators is functioning properly, and to check the operability of all the features available in the normal operating modes.

2.3.3.1 Test Requirements

The following items of laboratory equipment and supplies are required to conduct the operational performance tests:

1. A GEMINI administration set with an upper injection site. (Example: 2210)
2. IV Solution Container.
3. Standard IV Pole.
4. Communications Emulator plug (see Figure 2-2) [if communications option is installed].
5. Hemostat.
6. Empty fluid container.
7. Air-in-line simulator (see Figure 2-3).
8. **All except PC-1CE V8.xx 220V**. Empty Container Detector "A" **[use with Integer or Fractional Keypad PC-1s without ALARIS Medical P/N 10-1904-1 Installed]** or Universal ECD **[use with Titration Keypad and Integer or Fractional Keypad PC-1s with ALARIS Medical P/N 10-1904-1 installed]**.
9. Pressure gauge of at least 0-20 psig capability.

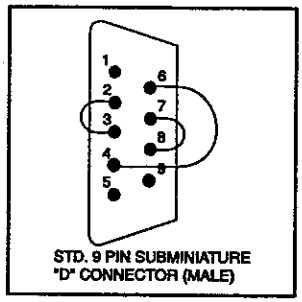


Figure 2-2. Communications Emulator Plug

2.3.3.2 Test Procedures

The following tests and associated procedures are presented in a sequence that provides an efficient, qualitative check of instrument operability.

INITIAL SETUP

1. Mount pump on IV pole (leave AC power cord unplugged).

2. Fill IV fluid container with water and hang on IV pole 24" (61 cm) above PC-1 pump/controller.

3. Spike and prime administration set.

4. Optional: Attach ECD sensor to the set drip chamber (do not connect to ECD receptacle until instructed).

5. Press POWER ON Control and check:
   - Battery Operation Indicator - Illuminated.
   - RATE and VTBI displays show ("888.8").
   - All LED indicators illuminate momentarily then extinguish, except the delivery mode/ operating indicator for the previously selected delivery mode and either "0" or "0.0" or "- - - -" in the units digit of Rate and VTBI displays.
   - "PC-1 Vx.xx" message scrolls once across the Status/Alarm Display (x.xx = software version).
   - A single audio Prompt sounds.
   - "SELECT P/C MODE" message scrolls once (if the P/C Mode select is unlocked) followed by continuous scroll of the "SET RATE" message. After 12 seconds the Prompt audio sounds.

Titration Keypad/Series v7.xx & subsequent Software

6. Press and hold the VOL INF control, then press POWER ON and check:
   - Battery Operation Indicator - Illuminated.
   - RATE and VTBI Displays show "888.8" momentarily then extinguish.
   - All LED indicators and dot-matrix elements illuminate momentarily then extinguish.
   - A single audio Prompt is sounded.
   - "setup PC-1 V7.xx (and subsequent) press setup control" scrolls continuously. (7.xx and subsequent) = installed software version).

7. Check or set instrument configuration:
   a. Press VOL INF control - "tamper-resistant mode" scrolls continuously
      - Press START - "enabled" or "disabled" displays statically.
      - Use either the ⇧ or ⇩ control to select "disabled" setting.

   b. Press VOL INF control - "P/C mode" scrolls continuously
      - Press START - "locked" or "unlocked" displays statically on the Operator Information display.
      - Selected Delivery mode/operating indicator illuminates.
      - Use either the ⇧ or ⇩ control to select "unlocked" setting.

   c. Press VOL INF control - "10 psi mode" or "517 mmHg mode" (v8.13 only) scrolls continuously
      - Press START - "enabled" or "disabled" displays statically.
      - Use either the ⇧ or ⇩ control to select "disabled" setting.

   d. Press VOL INF control - "macro/micro mode" scrolls continuously
      - Press START - "macro", "micro" or "mic/mac" displays statically.
      - Use either the ⇧ or ⇩ control to select "mic/mac".

   e. Press VOL INF control - "Primary switchover alert mode" scrolls continuously
      - Press START - "enabled" or "disabled" displays statically.
      - Use either the ⇧ or ⇩ controls to select "enabled".

f. Press VOL INF control - "communications setup" scrolls continuously
   - Press START - "serial #" displays statically.
   - Use 1, 10, 100 and/or CLEAR/SILENCE controls to input serial number.
   - Press PAUSE/STOP - "baudrate" displays statically.
   - Use either the ⌂ or ⌂ control to select baudrate (110, 300, 600, 1200, 2400, 4800 or 9600).
   - Press PAUSE/STOP - "parity" displays statically.
   - Use either the ⌂ or ⌂ control to select parity option (O [odd], E [even] or OFF)
   - Press PAUSE/STOP - "stopbits" displays statically.
   - Use either the ⌂ or ⌂ controls to select stop bit option (1 or 2).

g. Press VOL INF control - "language selection" scrolls continuously
   - Press START - currently selected language displays statically.
   - Use either the ⌂ or ⌂ control to select language option (english, german, french, italian, swedish, spanish).

h. Press VOL INF control "exit setup" scrolls continuously.

i. Press START to exit setup and enter infusion Setup and Operation mode
   - Battery operation LED flashes
   - Rate and VTBI displays show "- - - -".

CHARGING INDICATION (with PC-1 turned on)

1. Connect AC Power cord to a 120 or 220 VAC power source and check:
   - AC Power Indicator - illuminates.
   - Battery Operation Indicator - extinguishes.

2. Unplug AC Power cord from the AC power source and check:
   - AC Power Indicator - extinguishes.
   - Six pulses of the audio Alarm - sound **[v2.xx/5.xx/6.xx up to 6.55 ONLY]**.
   - Battery operation indicator - illuminates **[v2.xx/5.xx/6.xx up to 6.55 ONLY]** - flashes **[v6.55/v7.xx and subsequent]**.

3. Reconnect the AC Power cord to the AC power source.

NORMAL MODE OCCLUSION TESTS

1. Open the access door and check that the pumping mechanism homes.

2. Install the prepared GEMINI set and close the door. Ensure that the fluid level in the container is 24" above the height of the strain beam.

CONTROLLER MODE

3. Press the P/C MODE control to select Controller mode:
   - Controller mode delivery mode/operating indicator illuminates.

4. Press RATE control and check:
   - Last confirmed rate or "0" flashes in the rate display.
   - "SET RATE" scrolls continuously.

5. Use data entry controls to set rate to 125 mL/hr.
   - New rate flashes in rate display.
   - "SET VTBI" scrolls continuously.

6. Press VTBI control and check:
   - Last confirmed VTBI or "0" flashes in the VTBI display.

7. Use data entry controls to set VTBI to 50 mL.

8. Press START control and check:
   - Pumping mechanism operates.
   - Controller mode operating indicator flashes.
   - VTBI value decrements ≈2 mL/minute.

9. Use the hemostat to pinch off the tubing above the instrument and check for one of the following conditions (response is dependent upon microprocessor timing sequence):
   - "LOW FLOW" advisory - scrolls
   - Audio advisory - sounds
   - Pumping mechanism - stops

   or

   - "OCCLUDED" alarm scrolls
   - Alarm audio - sounds
   - Pumping mechanism - stops

10. Clear occlusion (remove hemostat), open door and allow pump to "home", close door and press START, then check:
    - Pumping mechanism - operates.
    - Operating indicator - flashes.
    - Alarm audio - silences.

11. Use hemostat to close off distal tubing and check:
    - "LOW FLOW" advisory scrolls
    - Advisory audio - sounds
    - Pumping mechanism - stops.

12. Within 45 seconds after "LOW FLOW" advisory begins, clear occlusion (remove hemostat) and verify:
    - Pumping mechanism - operates
    - Operating indicator - flashes.

PUMP MODE

13. Press P/C MODE control and change delivery mode to Pump:
    - Pump mode operating LED - illuminates.

14. Press START control and check:
    - Pump mode operating indicator - flashes.

15. Use the hemostat to close off the proximal tubing and check:
    - "OCCLUDED-FLUID SIDE" alarm - scrolls
    - Pump mode ALARM indicator - flashes
    - Alarm audio - sounds
    - Pumping mechanism - stops.

16. Clear occlusion (remove hemostat), then press START and check:
    - Pumping mechanism - operates
    - Operating indicator - flashes.

17. Use the hemostat to close off the distal tubing and check:
    - "OCCLUDED-PATIENT SIDE" alarm - scrolls
    - Pump mode ALARM indicator - flashes
    - Alarm audio - sounds
    - Pumping mechanism - stops.

18. Clear occlusion (remove hemostat), then press START and check:
    - Pumping mechanism - operates
    - Operating indicator - flashes.

19. Remove the set installed in step 2 under NORMAL MODE TESTS.

20. Install the fluid filled air-in-line simulator in the pump. Press syringe plunger to ensure the fluid level is above the air-in-line detector. Close the door and press START. Pump will operate normally, then extract plunger until air is in the air-in-line detector and check:
    - "AIR IN LINE" alarm - scrolls
    - Pump mode ALARM indicator - flashes
    - Alarm audio - sounds
    - Pumping mechanism - stops.

21. Upon test completion, remove the air-in-line simulator and re-install set removed in step 2.

PUMP PRESSURE TEST

1. Power down the PC-1 pump/controller and re-initialize instrument in the Maintenance/ Diagnostic Mode. Press and hold the COMPUTER CONTROL/MONITOR switch. Then press POWER ON.

2. Connect the distal tubing to the pressure gauge.

3. Press COMPUTER CONTROL/MONITOR switch to select "pump test".

4. Press START control twice.

5. Verify rate set to 125 mL/hr and VTBI >25 mL.

6. Press START control and allow the pump to operate for at least 30 seconds and wait until the peak pressure stabilizes.

7. Record the highest pressure reading obtained. **Resultant pressure must be ≥17 psi.**

<u>Software Release V6.xx Instruments & subsequent</u>
COMMUNICATIONS

1. Connect the Communications Emulator Plug to the RS-232-C Data Port.

2. Initialize the PC-1 pump/controller in the Maintenance/Diagnostic Mode (see Section 5 for procedure).
    - "Maintenance Vx.xx" or "Diagnostic Vx.xx and subsequent", and "To Exit Press STOP" messages scroll. (x.xx = installed software release).

3. Press COMPUTER CONTROL/MONITOR control 6 times and check:
    - "serial port test" message scrolls continuously.

4. Press START control and check:
    - "echo" message displays statically

or

- " ◀ ◀ " - displays statically in the operator information display and "PLUG" appears in the VTBI display.

5. Press COMPUTER CONTROL/MONITOR control twice to return to the "Maintenance Vx.xx" [**v2.xx/5.xx/6.xx**] or "Diagnostic Vx.xx" [**v7.xx and subsequent**] message.

6. Press PAUSE/STOP control to exit the Maintenance Mode and power down the instrument.

7. Remove the Communications Emulator Plug from the RS-232-C Data Port.

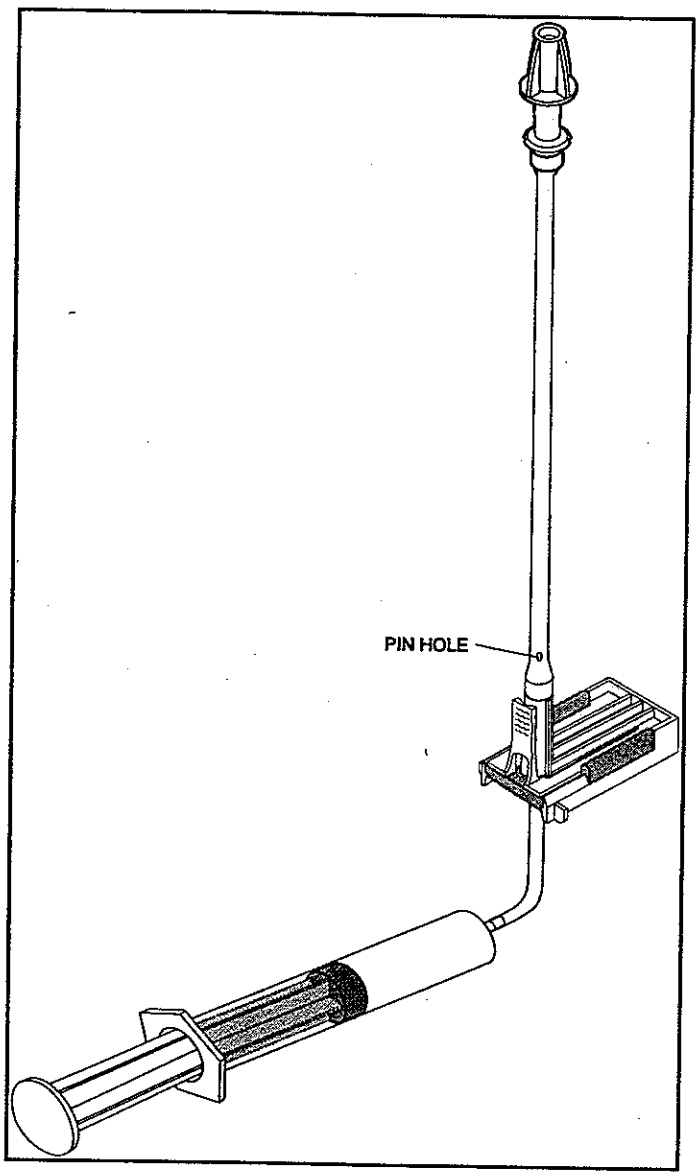


Figure 2-3. Air-In-Line Simulator

PC-1 PUMP/CONTROLLER TEST DATA SHEET

Instrument Serial No._____ Software Version _____

Date _____ Technician _____

Test No.	Description	Reference	Record Result	Pass/Fail
1	Electrical Leakage Test	2.3.2.1	_____	Pass___/Fail___
2	Electrical Ground Test	2.3.2.2	_____	Pass___/Fail___
3	Initialization	2.3.3.2	_____	Pass___/Fail___
4	Keypad and Display Check	2.3.3.2	_____	Pass___/Fail___
5	Controller Mode Operation	2.3.3.2	_____	Pass___/Fail___
	Slide Clamp Detector	2.3.3.2	_____	Pass___/Fail___
6	Pump Mode Operation	2.3.3.2	_____	Pass___/Fail___
	Air-In-Line	2.3.3.2	_____	Pass___/Fail___

Figure 2-4. PC-1 Pump/Controller Test Data Sheet

SECTION 3 - OPERATION

3.1 INTRODUCTION

This section describes the recommended procedures for operation of the IMED® GEMINI PC-1® Volumetric Infusion Pump/Controller ("PC-1"). The information is intended to provide maintenance technicians with a basic understanding of instrument operation including the audio and visual status/alarm system.

NOTE

Although the PC-1 pump/controller is built and tested to exacting specifications, it is not intended to replace the role of medical personnel in the supervision of IV infusions. The user is urged to exercise vigilance in the utilization of the PC-1 pump/controller.

3.2 CONTROLS AND INDICATORS

The keypad controls and indicators used to set up and operate the PC-1 pump/controller are illustrated in Figures 3-1, 3-1a and 3-2. The functional descriptions of the controls and indicators are listed in Table 3-1.

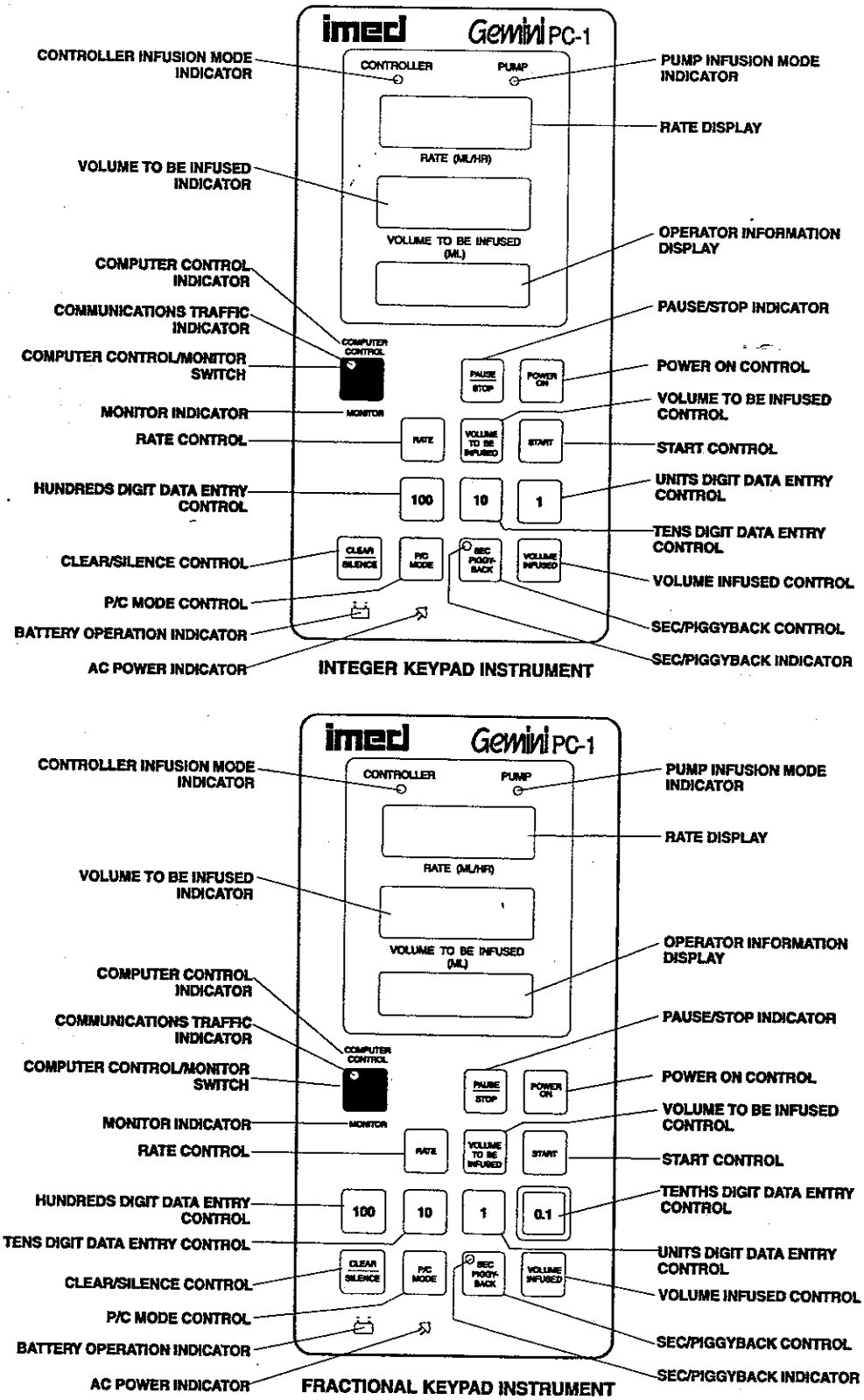


Figure 3-1. PC-1 Pump/Controller Front Panel Controls and Indicators

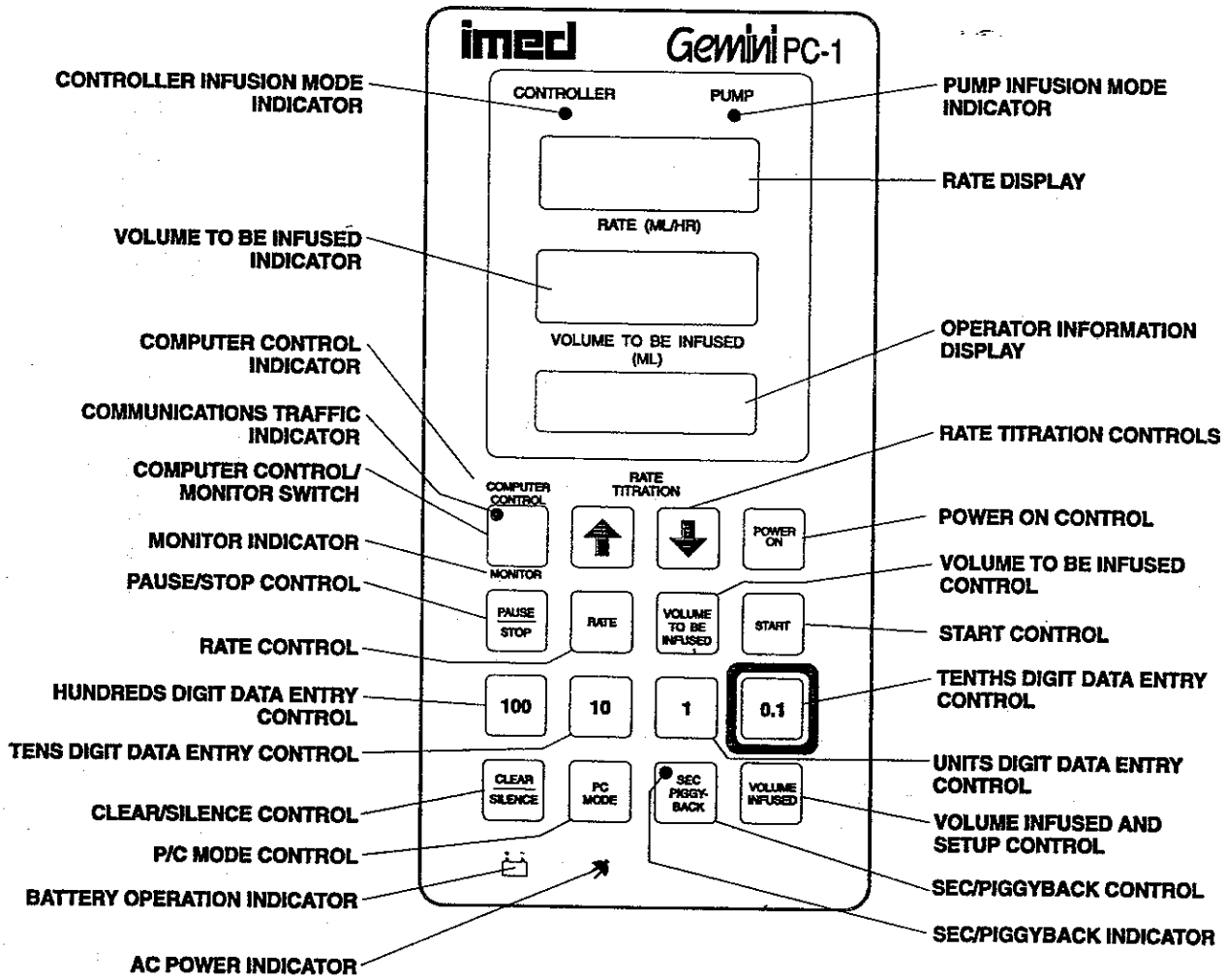


Figure 3-1a. PC-1 Pump/Controller Titration Front Panel Controls and Indicators

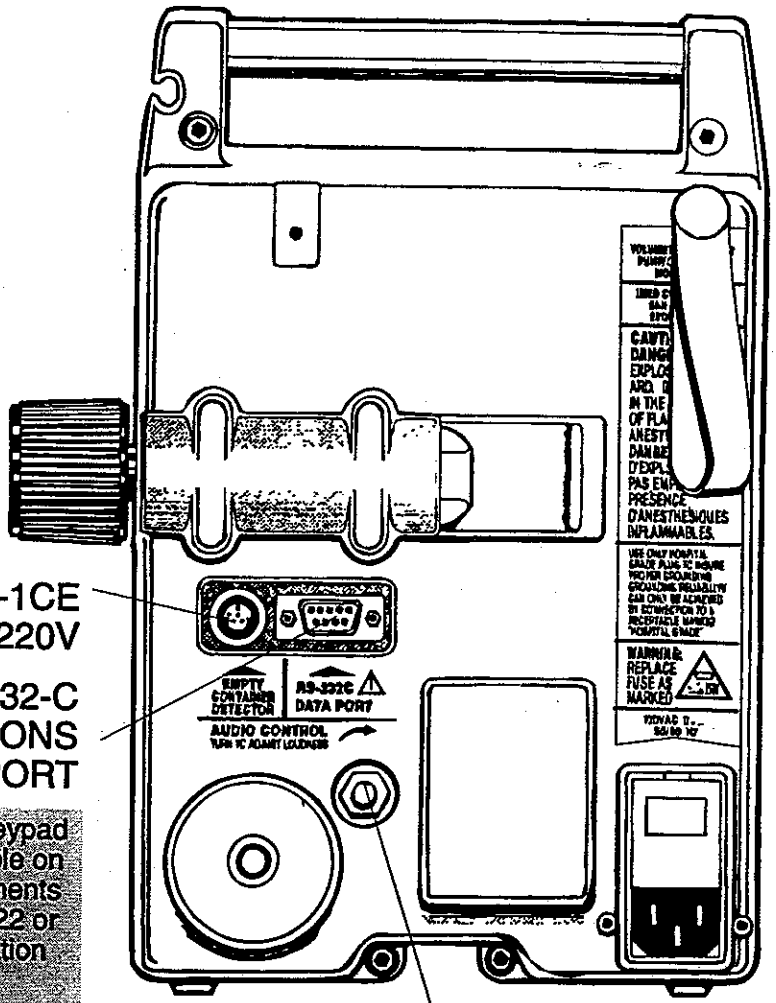

ECD - All except PC-1CE
V8.xx 220V
RS-232-C
COMMUNICATIONS
DATA PORT
Not Installed on Integer Keypad Instruments ONLY available on Fractional Keypad Instruments with Software Release 6.22 or higher. Standard on Titration Keypad Instruments
AUDIO CONTROL [v2.xx/5.xx/6.xx]
plus TAMPER RESISTANCE [v7.xx/8.xx]

Figure 3-2. PC-1 Pump/Controller Rear Panel Controls and Indicators

Table 3-1. PC-1 Pump/Controller Controls and Indicators

Control/Indicator	Functional Description
FRONT PANEL	
CONTROLLER Delivery Mode/Operating Indicator	LED indicator. LED illuminates when power is on and the Controller delivery mode selected. When infusing, LED flashes to indicate instrument is operating.
PUMP Delivery Mode/Operating Indicator	LED indicator. LED illuminates when power is on and the Pump delivery mode selected. The Versataper function is active when in Pump delivery mode. When infusing, LED flashes to indicate the instrument is operating.
RATE Display	Four digit, 7-segment plus decimal LED Displays. Displays rate infusion parameter for selected operating state (Primary or Secondary). Following initialization "0" or "0.0" or "- - - -" displays. Display flashes last confirmed rate when RATE control is actuated. Display changes to steady when Rate value is confirmed by subsequent keypad action.
Volume to be Infused (VTBI) Display	Four digit, 7-segment plus decimal LED displays. Displays VTBI infusion parameter for selected operating state (Primary or Secondary). Following initialization "0" or "0.0" or "- - - -" displays. Display flashes last confirmed VTBI when VTBI Control is actuated. Display changes to steady when VTBI value is confirmed. Flashes Total Volume Infused for ≈6 seconds following a single actuation of the VOLUME INFUSED and Secondary Volume infused when VOLUME INFUSED is pressed twice.
Operator Information (Status/Alarm) Display	Eight position dot-matrix display. Scrolls PROMPT, ADVISORY, ALARM and MALFUNCTION messages during Normal operation. Presents scrolled and/or static Maintenance mode test selections, conditions and status reports.
COMPUTER CONTROL Indicator	Backlighted indicator. Flashes when the PC-1 pump/controller is enabled for computer control operation. Illuminates steadily when PC-1/host computer communication is confirmed.
COMPUTER CONTROL/MONITOR Switch	Alternate action type switch. When pressed, selects either Monitor or Computer Control operating condition. Operable only when the computer interface cable is connected. Used in conjunction with POWER ON to initialize the instrument in the Maintenance/Diagnostic Mode and to sequence through the maintenance mode test loop.
MONITOR Indicator	Backlighted indicator. Illuminates when the communication interface cable is connected to the RS-232-C Communications Data Port.
Communications Traffic Indicator	LED indicator. Flashes when communications traffic through the RS-232-C data link is active. Operable only during Monitor and Computer Control operation.

Table 3-1 (cont.). PC-1 Pump/Controller Controls and Indicators

Control/Indicator	Functional Description
PAUSE/STOP Control	Momentary contact type switch. When actuated once, puts the instrument into the Pause condition. If infusing, pumping will stop. After 2 minutes in Pause, the "PRESS START" visual and audio prompt will initiate. Second actuation shuts down the instrument. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed while in the VersaTaper Setup mode, enters all programmed VersaTaper parameters and initiates the scrolling of the VersaTaper setup summary message.
RATE Control	Momentary contact type switch. When pressed, enables entry, change or clearing of the rate infusion parameter. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed while in the VersaTaper mode, causes display to sequence through the programmed steps to review programmed parameters.
VOLUME TO BE INFUSED (VTBI) Control	Momentary contact type switch. When pressed, enables entry, change or clearing of the VTBI infusion parameter. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed in conjunction with the POWER ON control, initializes the instrument in VersaTaper: Setup mode. **Titration Keypad/Series v7.xx & Subsequent Software** When pressed in conjunction with the POWER ON control, initializes the instrument in VersaTaper: Setup (includes AutoTaper and AutoTaper Patient) mode.
RATE TITRATION Controls	**Titration Keypad/Series V7.xx & Subsequent Software** Momentary contact-type switches. When pressed, will increase or decrease the rate parameter 1 mL/hr (MACRO) or 0.1 mL/hr (MICRO) with each keypress, or will scroll the rate up or down when pressed and held.
START Control	Momentary contact type switch. When pressed, starts the pumping mechanism. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed while in VersaTaper: Setup mode, advances the displayed step to the next step.
POWER ON Control	Momentary contact type switch. When pressed, applies electrical power to the PC-1 pump/controller. In the event of a hardware malfunction, identified by continuous audio, actuating POWER ON will remove electrical power from all circuits not connected to $+5V_{(PROT)}$ (and silence malfunction audio).

Table 3-1 (cont.). PC-1 Pump/Controller Controls and Indicators

Control/Indicator	Functional Description
CLEAR/SILENCE Control	Momentary contact type switch. When pressed subsequent to actuating the RATE, VTBI or VOLUME INFUSED controls, clears the corresponding display for the selected channel. When pressed, while Alarm or Prompt audio is sounding, will temporarily silence the audio for 2 minutes; when internal instrument protocol permits. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed in conjunction with the POWER ON control, will return the instrument to normal (non-VersaTaper and AutoTaper) operation.
Hundreds & Thousands (100) Digit Data Entry Control	Momentary contact type switch. Single actuation subsequent to actuating the RATE or VTBI controls increments the hundreds digit of the corresponding display. When pressed and held, allows the hundreds digit to increment automatically. The hundreds digit upon reaching 9 rolls over to 0 and increments the thousands digit by 1. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed in conjunction with the POWER ON control, will initialize the instrument in the MACRO mode or toggle mode to UNIVERSAL if previously in MACRO mode.
Tens (10) Digit Data Entry Control	Momentary contact type switch. When pressed subsequent to actuation of the RATE or VTBI control, increments the tens digit of the corresponding display. Display rolls over 9 to 0. **Fractional Keypads/Series V6.xx and Subsequent** When pressed in conjunction with the POWER ON control, invokes the 10 psi occlusion pressure lock feature. **Software Release v8.13 only** When pressed in conjunction with the POWER ON control, invokes the 517 mmHg occlusion pressure lock feature.
Units (1) Digit Data Entry Control	Momentary contact type switch. When pressed subsequent to actuation of the RATE or VTBI control, increments the units digit of the corresponding display. Display rolls over 9 to 0.
Tenths (0.1) Digit Data Entry Control	**Fractional Keypad/Series V5.xx and Subsequent Software** Momentary contact type switch. When pressed subsequent to actuation of the RATE or VTBI control, increments the tenths digit of the corresponding display. Display rolls over from 0.9 to 0.0. When pressed in conjunction with the POWER ON control, initializes the instrument in the MICRO mode or toggles mode to UNIVERSAL if previously in MICRO mode.

Table 3-1 (cont.). PC-1 Pump/Controller Controls and Indicators

Control/Indicator	Functional Description
Battery Operation Indicator	Backlighted indicator. Illuminates steadily when the PC-1 pump/controller is operating on battery power **[v2.xx through 5.18]**. Flashes when PC-1 pump/controller is operating on battery power **[v5.59 and subsequent]**.
P/C (Delivery) MODE Control	Alternate action type switch. When pressed, changes the delivery mode between Pump and Controller. When pressed in conjunction with the POWER ON control invokes the P/C Mode lockout feature. **Fractional Keypad/Series V5.xx & Subsequent Software** When pressed in conjunction with the START control while in the VersaTaper mode, initiates a VersaTaper infusion.
SEC/PIGGYBACK Control	Alternate action type switch. When pressed, enables the instrument in the Secondary state allowing Secondary infusion parameters to be programmed and a Secondary infusion to be initiated.
Sec/Piggyback Indicator	LED indicator. Flashes when the instrument is in the Secondary state. Illuminates steadily when the instrument is performing a secondary infusion.
VOLUME INFUSED Control	Momentary contact type switch. When actuated, causes the Total Volume Infused value to flash for 6 seconds on the VTBI display and scroll the "TOTAL VOL INFUSED" message once. When pressed twice with the instrument in the Secondary mode, will cause the Secondary Volume Infused to flash for 6 seconds on the VTBI display and scroll "SEC VOL INFUSED" once. Used by Biomedical and other specially trained personnel to access the SETUP mode to configure the instrument for specific operating modes.
AC Power Connected Indicator	Backlighted Indicator. Illuminates when the PC-1 pump/controller is connected to an external AC power source.
REAR PANEL	When rotated, varies audio output volume; when protocol permits.
Integer/Fractional Keypad Instruments AUDIO CONTROL	
Titration Keypad Instruments AUDIO/TAMPER-RESISTANT CONTROL	Dual action switch/potentiometer. When rotated, varies the audio volume when permitted; when pressed, silences audio alarm for ≈2 minutes. When pressed and held for 3 seconds with the tamper-resistant feature enabled, will lock out all of the keypad controls except VOLUME INFUSED, SEC/PIGGYBACK and CLEAR/SILENCE. A repeat 3 second actuation will unlock the keypad controls.
220V **AC Power Interrupt Switch** (if installed)	Rocker type switch used to apply and interrupt AC voltage to the instrument for operation of the battery charging and control circuits.

3.3 OPERATING CONDITIONS

The PC-1 pump/controller can be operated independently (Normal Operation) or as a computer controlled device (Computer Operation) when the communications option is installed. Normal operation includes the two patient care delivery modes - Pump and Controller plus a Maintenance mode which is provided for use by bio-medical personnel to service the instrument. Computer operation encompasses a Monitor and Computer Control mode. Operating procedures for both normal and computer operation are described in detail in paragraph 3.3.1.1 below. Procedures unique to a specific operating mode are enclosed in a box. Operations that may be performed from the host computer terminal are identified by a Ⓒ in the left margin. Maintenance mode capability is addressed briefly in paragraph 3.3.2 of this section and operating details are provided in paragraph 5.3.2 of Section 5.

3.3.1 Normal and Computer Operation

A tactile keypad and visual displays comprise the user interface. The keypad is used to power up and configure the instrument, to enter and/or change infusion parameters, to start the instrument, and to pause and/or stop instrument operation.

Integer/Fractional Keypad Instruments
Tamper-resistant operation is achieved through the requirement to actuate the appropriate control keys in a prescribed sequence.

Titration Keypad Instruments
Tamper-resistant operation (keypad lockout) is enabled in the SETUP mode and selected/ deselected by using the press feature of the Audio Control switch.

3.3.1.1 Pump and Controller Modes

The decision to use the PC-1 instrument in the Pump or Controller delivery mode for specific IV infusions resides with the patient's attending medical personnel. If desired, the PC-1 pump/controller can be locked into either the Pump or Controller mode. The instrument's occlusion pressure sensing is predicated on the delivery mode selected and the head height of the IV solution container. With the recommended 24 inch (61 cm) head height and the instrument operating in the Controller mode, an occlusion will be sensed when the distal tubing in-line pressure exceeds container height pressure by ±12 inches (30 cm) of container height. In the Pump mode, occlusion pressure is pre-set to 10 ±2 psi (69 ±14 kPa) [IV container height is less critical]. The procedural steps described in the following paragraphs pertain to both normal and computer operating conditions. Procedures unique to a specific operating condition(s) are enclosed in a frame.

Setup and Operating Procedures

1. Connect the PC-1 pump/controller to an external AC power source using the power cord supplied by ALARIS Medical. It is recommended that the power cord remain plugged into the instrument at all times.

WARNING

Prior to reattaching the AC power cord to the instrument, ensure the male base of the power input module is clean of any electrolyte and thoroughly dry. Check the female contacts on the power cord connector for presence of any electrolyte; if contaminated, replace the power cord.

Monitor and Computer Control Operation

- Ensure the computer communications parameters for the host computer and the PC-1 are set up and the communications interface cable is connected to the RS-232-C Communications Data Port.

1a. 220V Turn the AC Power Interrupt switch on (where applicable).

2. Press the POWER ON control and check:
   - All indicators illuminate, all segments of the RATE and VTBI displays illuminate ("888.8"); the Operator Information display remains blank.
   - "PC-1 Vx.xx" scrolls once across the operator information display (x.xx represents the installed software revision).
   - Keyclick audio sounds once.
   - The Delivery Mode/Operating LED illuminates according to the previously selected delivery mode.
   - "SELECT P/C MODE" will scroll once, if the P/C Mode lockout has not been invoked.

Integer Keypad/Series V2.xx Software

- Rate and VTBI displays will show a "0" in the units digit display and "SET RATE" prompt begins scrolling. After 12 seconds, Audio Prompt will begin.

Fractional Keypad/Series V5.xx & Sub. Software

- In the Universal or MACRO mode, the Rate and VTBI display will show a "0" in the unit digit display. In MICRO, or UNIVERSAL mode subsequent to a MICRO selection, the Rate and VTBI displays will show "0.0" in the unit and tenths digit displays. "SET RATE" will begin scrolling followed by "MACRO" or "MICRO" as appropriate to the selected mode. After 12 seconds, the Audio Prompt will begin.

Titration Keypad/Series v7.xx & subsequent Software

- Rate and VTBI displays will show "- - - -". "SELECT P/C MODE" will scroll once, if not locked; "SET RATE" will begin scrolling followed by "MICRO" or "MACRO", if appropriate. After 12 seconds, the Audio Prompt will begin.

Monitor and Computer Control Operation

- Monitor indicator illuminates

NOTE

After 2 minutes, the PC-1 pump/controller will automatically shutdown unless the instrument is in an alarm condition, a control key is actuated or the COMPUTER CONTROL/MONITOR switch is pressed.

3. Prepare the IV fluid container following accepted hospital procedure.

4. Open the GEMINI administration set package, remove set, and close the roller clamp.

5. Insert the set spike into the fluid container and hang the IV container 24 inches (61 cm) above the instrument following accepted hospital procedure.

6. Fill the drip chamber to approximately (2/3 full).

7. Open the roller clamp slowly to prime and clear all air from the injection sites and tubing fitments.

8. Close the roller clamp.

9. Open the door and insert the upper tubing fitment into the recess above the pump mechanism. Using care to avoid stretching the pumping segment, insert the Flo-Stop fitment into the AIL/SCD recess below the pump mechanism with the arrow pointing into the pump. Press the tubing into the air-in-line detector. Close the door. Follow the specific instructions included with the set.

10. Open the roller clamp.

Computer Control Operation

Press the COMPUTER CONTROL/ MONITOR switch:

- The COMPUTER CONTROL indicator flashes
- The MONITOR indicator extinguishes
- When communications are established, the COMPUTER CONTROL indicator will change to steady
- During two-way communications between the PC-1 and host computer, the Communications Traffic indicator will flash.

Enter parameters, initiate and stop the infusion from the host computer using the C2 Communications Protocol operators described in the ALARIS Medical Systems C2 Programmer's Guide.

11. Press the P/C MODE control to set the delivery mode **(selection not available if P/C Mode lockout is invoked)**.
    - The appropriate delivery mode indicator illuminates.

12. Set the RATE and VTBI. Ⓒ

    a. Press the RATE control and check:
    - The last entered rate flashes on the display.
    - The "SET RATE" prompt continues to scroll.

Fractional Keypad/Series V5.xx & Sub. Software

NOTE

In MACRO or UNIVERSAL mode with rate ≥100 mL/hr, the tenths (0.1) control is not functional. In MICRO or UNIVERSAL mode with the rate in tenths, the hundreds (100) control is not functional. In UNIVERSAL mode, pressing CLEAR/SILENCE will enable entry of either tenths or hundreds parameters.

b. Use the data entry controls to set/change rate:
   - The "SET RATE" prompt extinguishes.
   - The new rate flashes on the display.

c. Press the VTBI control and check:
   - The new rate displays steadily on the display.
   - The last entered VTBI flashes on the display.
   - The "SET VTBI" prompt continues to scroll.

Fractional Keypad/Series V5.xx & Sub. Software

NOTE

In MACRO mode, the tenths (0.1) control is not functional. In UNIVERSAL mode with Rate set to a fractional value, the VTBI will be confirmed and displayed as a fractional value and will decrement in 0.1 mL increments.

d. Use the data entry controls to change VTBI:
   - The "SET VTBI" prompt extinguishes.
   - The new VTBI flashes on the display.
   - The "PRESS START" prompt begins scrolling after 5 seconds followed by the audio prompt.

NOTE

All except PC-1 CE V8.xx 220V. A VTBI selection of "ALL" is only available when an Empty Container Detector (ECD) is connected to the instrument.

13. Attach the set to the patient's indwelling venipuncture device following accepted hospital procedure.

14. Press the START control. (C)
    - The delivery mode and infusion parameters are entered.
    - The infusion is started.
    - The VTBI displays steadily on the display.
    - The "PRESS START" prompt extinguishes.
    - The audio prompt silences.
    - The delivery mode/operating indicator flashes.

Verify the delivery mode/operating indicator is flashing. This is the positive indication.

During infusion:
- The VTBI decrements.
- The volume infused increments (not displayed).
- Various Advisories, Alarms, and Malfunctions may be displayed. Refer to the Operator Information Display and Alarm Response Procedures section in this manual for an explanation and appropriate response.

Upon completion of the infusion:
- An audio prompt sounds.
- The "INFUSION COMPLETE-KVO" or the "EMPTY CONTAINER-KVO" advisory, as appropriate, scrolls continuously across the display.
- A KVO infusion is initiated.

Integer Keypad/Series V2.xx Software

KVO rate is 1 mL/hr.

Fractional Keypad/Series V5.xx & Sub. Software

KVO rate is 1 mL/hr for infusion rates ≥1 mL/hr or the set rate for rates <1.0 mL/hr.
- The RATE display shows the KVO rate.
- The delivery mode/operating indicator continues to flash.

NOTE

The following detailed operating procedures apply to all instrument configurations and operation in either the Pump or Controller delivery mode. Procedures that are compatible with Computer Controlled operation are identified with a (C) and are performed using C2 Communcations Protocol Commands and/or Queries (See ALARIS Medical Systems Programmer's Guide for C2 Communications Protocol).

Pausing an Infusion

1. Press the PAUSE/STOP control once.
   - The infusion stops.
   - The delivery mode/operating indicator illuminates steadily according to the delivery mode selected.
   - The audio prompt silences (if active).
   - An Advisory audio sounds repeatedly after 15 seconds.
   - The "SET RATE" or "SET VTBI" prompts extinguish.
   - The "PAUSE" advisory continuously scrolls.
   - After 2 minutes, the "PRESS START" prompt begins scrolling, Advisory audio ceases and Prompt audio begins.
2. Press the START control to resume the infusion.
   - The infusion is resumed.
   - The "PAUSE" advisory extinguishes.

Stopping a Primary Infusion

1. Press the PAUSE/STOP control twice.
   - Operator information display shows "OFF n", where "n" represents a count down timer. The display counts down from "3" to "1". After reaching "1", the PC-1 pump/controller powers down.
   - The infusion stops.
   - The delivery mode/operating indicator extinguishes.
   - Rate and VTBI displays go blank.
   - Active messages extinguish.
   - Active audio ceases.

Titrating Rate

1. Repeatedly press the ⍓ or ⍗ control to change the rate parameter in 1 or 0.1 mL/hr increments, or press and hold the ⍓ or ⍗ control to scroll quickly to a new rate parameter.
   - Rate display will flash the rate as the selection changes.
   - After 5 seconds, the "PRESS START" prompt starts scrolling.
2. Press START.
   - The new rate is entered and displays steadily.
   - The instrument begins to infuse at the new rate.

Changing Rate or VTBI During Infusion

1. Press the RATE control to change rate.
   - The last confirmed rate flashes on the display.
   - After 5 seconds, "SET RATE" message begins scrolling.
2. Use the appropriate data entry controls, or the ⍓ or ⍗ controls to change rate.
   - The "SET RATE" message extinguishes.
   - The new rate flashes on the display.
3. Press the VTBI control to change VTBI.
   - The new rate displays steadily.
   - The current decremented VTBI flashes on the display.
   - After 5 seconds, "SET VTBI" message begins scrolling.
4. Use the appropriate data entry controls to change VTBI.
   - The new VTBI flashes on the display.
   - The "SET VTBI" message extinguishes.
5. Press the START control.
   - The new infusion parameters are confirmed.
   - The infusion resumes at the new infusion parameters.
   - The new VTBI displays steadily.

Changing Delivery Mode During Infusion (P/C Mode unlocked)

1. Press the P/C MODE control.
   - The delivery mode/operating indicator illuminates according to the new delivery mode selected.
   - The delivery mode/operating indicator for the previously entered delivery mode continues to flash.
2. Press the START control.
   - The new delivery mode is confirmed.
   - The infusion resumes in the new delivery mode.

Restarting an Infusion Following an "INFUSION COMPLTE-KVO" or "EMPTY CONTAINER-KVO" Advisory

1. Press the P/C MODE control to change delivery mode, if a delivery mode change is desired.

2. Press the RATE control and use data entry controls to change rate.

3. Press the VTBI control and use data entry controls to change VTBI.

   Software Release V6.xx and V7.xx
   All except PC-1 CE V8.xx 220V. When an ECD is connected, either the Rate or VTBI control must be pressed prior to pressing START to avoid confirming KVO as the new rate.

4. Press the START control.
   - The new infusion parameters are confirmed and displayed.
   - The infusion is started.
   - The "INFUSION COMPLETE-KVO" or "EMPTY CONTAINER-KVO" message extinguishes.

To View Total and/or Secondary Volume Infused Ⓒ

1. Press the VOLUME INFUSED control once.
   - The Total Volume Infused will flash on the VTBI display for 6 seconds.
   - The "TOTAL VOL INFUSED" message scrolls once.

2. Press the VOLUME INFUSED control twice while the PC-1 pump/controller is in Secondary mode.
   - The Secondary Volume Infused will flash on the VTBI display for 6 seconds.
   - The "SEC VOL INFUSED" message scrolls once.

To Clear Total and Secondary Volume Infused Ⓒ

1. Press VOLUME INFUSED control.
   - The Total Volume Infused will flash on the VTBI display.

2. Press CLEAR control while Volume Infused display is flashing.
   - The Total and Secondary Volume Infused displays reset to "0".

3. Press START control.

Setting Up Secondary (Piggyback) Infusion With Dual Rates

1. Set up the Primary infusion (using a check valve administration set) as previously described. The Secondary infusion may be set up prior to or after starting a Primary infusion.

2. Prepare the Secondary fluid container following accepted hospital procedure.

3. Open the GEMINI Secondary administration set package, remove set, and close clamp.

4. Insert the set spike into the fluid container and hang the Secondary container following accepted hospital procedure.

5. Attach the needle to the Secondary set.

6. Fill the drip chamber at least 2/3 full.

7. Open clamp and prime the set. Close clamp.

8. Insert the Secondary set needle into the upper injection site on the Primary set.

9. Lower the **Primary** fluid container using the hanger provided with the Secondary set.

10. Open the clamp on the Secondary set.

11. Press the SEC/PIGGYBACK control.
    - Primary infusion continues unabated.
    - The SEC/PIGGYBACK indicator flashes.
    - The RATE and VTBI displays show "SEC".
    - The "SET RATE" message begins scrolling.

12. Press the RATE control.
    - The last confirmed rate flashes.
    - The "SET RATE" message continues to scroll.
    - The "SET VTBI" message begins scrolling.

13. Use the appropriate data entry controls to set or change Secondary rate.
    - The "SET RATE" message is cancelled.
    - The new Secondary rate flashes in the Rate display.

14. Press the VTBI control.
    - The new Rate is confirmed and displays steadily.
    - The last confirmed VTBI flashes.
    - The "SET VTBI" message continues to scroll.
    - The "PRESS START" message begins to scroll.

15. Use the appropriate data entry controls to set or change Secondary VTBI.
    - The "SET VTBI" message is cancelled.
    - The new Secondary VTBI flashes on the display.

16. Press the START control.
    - The new VTBI is confirmed and displays steadily.
    - The instrument operation changes to the Secondary infusion parameters.
    - The "SECONDARY" message begins continuous scrolling.
    - The SEC/PIGGYBACK indicator illuminates steadily.

NOTE

Verify that the VTBI setting does not exceed the contents of the Secondary fluid container.

During Secondary infusion:
- The Secondary VTBI decrements.
- The Secondary volume infused increments (not visible).

Upon completion of the Secondary infusion:
- The Changeover audio sounds (if enabled).
- The instrument switches over to the Primary infusion parameters.
- The preset Primary rate and VTBI display steadily on the displays.
- The SEC/PIGGYBACK indicator extinguishes.
- The "SECONDARY" message extinguishes.
- The "PRIMARY" message begins scrolling.

NOTE

If the Secondary VTBI parameter is set at a value less than the volume of fluid in the secondary container, there will be fluid remaining in the secondary container when the instrument changes over to primary infusion parameters. This residual fluid will be infused at the primary rate. When the fluid level in the secondary set is at the same level as the fluid in the primary set drip chamber both solutions will infuse simultaneously until the secondary set is empty.

Viewing Primary Infusion Parameters During Secondary Infusion (C)

1. Press SEC/PIGGYBACK control.
    - Primary RATE and VTBI parameters will flash on the respective displays for 6 seconds.

Changing Primary Infusion Parameters During Secondary Infusion (C)

1. Press the SEC/PIGGYBACK control.
    - The Secondary infusion continues unabated.
    - The SEC/PIGGYBACK indicator flashes.
    - The last confirmed Primary Rate and VTBI flash on the displays.
    - The "SECONDARY" message is suppressed.
    - The "PRIMARY" message scrolls.
2. Press the RATE control and use the data entry controls to change the Primary rate.
    - The "SET RATE" and "PRESS START" messages begin scrolling.
    - Last confirmed VTBI displays steadily.
    - Newly entered Primary rate value flashes.
    - The "SET RATE" message is cancelled and "SET VTBI" begins scrolling.
3. Press the VTBI control and use the data entry controls to change the Primary VTBI setting.
    - The last confirmed Primary VTBI value flashes.
    - The new Rate value displays steadily.
    - Newly entered Primary VTBI value flashes.
    - The "SET VTBI" message is cancelled.
4. Press the SEC/PIGGYBACK control.
    - The new infusion parameters are confirmed.
    - The SEC/PIGGYBACK indicator illuminates steadily.
    - The "SECONDARY" message resumes scrolling.
    - The "PRIMARY" message is cancelled.

Stopping a Secondary Infusion and Returning to Primary Infusion

1. Close Secondary set clamp.
2. Press the SEC/PIGGYBACK control.
3. Press the START control:
    - The Secondary infusion stops.
    - The Primary infusion starts.
    - The Primary rate and VTBI display steadily on the respective displays.
    - Changeover audio sounds (if enabled).

All except PC-1CE V8.xx 220V. Infusing Using an Empty Container Detector (ECD)

1. Set up a Primary infusion.
2. Connect an ECD to the PC-1 ECD connector and attach the ECD sensor to the drip chamber of the Primary set.
3. Set the Primary VTBI to "ALL" by clearing the VTBI and pressing the 1 data entry control once.
4. Press the START control. When an empty container is detected:
   - Audio prompt sounds.
   - The "EMPTY CONTAINER-KVO" message scrolls continuously.
   - A KVO infusion is initiated.
   - The RATE display shows the KVO rate.

Clearing Alarms

1. Check the operator information display to determine the alarm condition.
2. Refer to the Operator Information Display and Alarm Response Procedures (Section 3.4) in this manual for the proper procedures for responding to a specific alarm condition.

TURNING OFF THE PC-1 PUMP/CONTROLLER

1. Press the PAUSE/STOP control twice to terminate an infusion.
   - Operator information display shows "OFF n", where "n" represents a count down timer. The display counts down from "5" **[v2.xx through v6.xx]** or "3" **[v7.xx and subsequent]** to "1" . After reaching "1", the PC-1 pump/controller powers down.
   - The infusion stops.
   - The delivery mode/operating indicator extinguishes.
   - Active messages extinguish.
   - Active audio ceases.
   - Rate and VTBI displays go blank.

NOTE

To interrupt the power down sequence, press PAUSE/STOP control on the keypad. To resume an infusion press START, then ensure the delivery mode/operating indicator is flashing.

Computer Control Operation

- At the instrument, press the COMPUTER CONTROL/MONITOR switch. The Computer Control indicator will extinguish and the MONITOR indicator will illuminate, then proceed as above for non-computer operation.

NOTE

In the event of a hardware-detected malfunction (evidenced by constant audio), the POWER ON control must be pressed to silence the audio and interrupt instrument electrical power. Pressing the POWER ON control a second time will re-power the instrument and allow normal shut down procedures to be employed. If the malfunction can not be circumvented, the instrument will require technical personnel to silence the alarm and deactivate the electrical circuit. In the event of a software-detected malfunction, i.e., a HELP message appearing in the operator information display, the PC-1 pump/controller must be turned off by pressing the PAUSE/STOP control.

Locking and Unlocking the P/C MODE Control

1. To Lock - while depressing the P/C MODE control, press POWER ON to initialize the instrument. The delivery mode previously selected will be locked-in.
2. To Unlock - powerdown the instrument, simultaneously depress the P/C MODE control and press POWER ON to initialize. The P/C MODE control will be restored to normal operation.

<u>Fractional/Titration Keypad Instruments</u>
Locking and Unlocking the MICRO Delivery Mode

1. To Lock - With the instrument off, press and hold the tenths (0.1) key then press POWER ON. After initialization, release the tenths key:
   - "MICRO" message will scroll following the "SELECT P/C MODE" message or "PC-1 Vx.xx" if P/C Mode lockout is invoked.
   - "MICRO" message will cancel once the RATE control has been pressed.
   - RATE and VTBI displays will appear in the "0.0" format.

2. To Unlock - With the instrument off, press and hold the tenths (0.1) key then press the POWER ON control. Following initialization, release the tenths key:
   - The instrument is now in UNIVERSAL mode
   - RATE and VTBI displays will appear in either the "0.0" or "0" format depending upon the Universal mode RATE and VTBI parameters selected.

Locking and Unlocking the MACRO Delivery Mode

1. To Lock - with the instrument off, press and hold the hundreds (100) key then press POWER ON. Following initialization, release the hundreds key:
   - "MACRO" message will scroll following the "SELECT P/C MODE" message or "PC-1 Vx.xx" if P/C Mode lockout is invoked.
   - "MACRO" message will cancel once the RATE control has been pressed.
   - RATE and VTBI displays will appear in the "0" format.

2. To Unlock - with the instrument off, press and hold the hundreds (100) key then press the POWER ON control. Following initialization, release the hundreds key:
   - The instrument is now in UNIVERSAL mode.
   - RATE and VTBI displays will appear in either the "0.0" or "0" format, depending on the RATE and VTBI parameters selected.

Software Release V6.xx and Subsequent

Locking and Unlocking the 10 PSI/517 mmHg mode.

1. To Lock - With the instrument off, press and hold the tens (10) key then press POWER ON. After initialization release the tens key:
   - "10 PSI" or "517 mmHg" (v8.13 only) message will scroll until the START control is actuated.

2. To Unlock - With the instrument off, press and hold the tens (10) key then press the POWER ON control. Following initialization, release the tens key.

Software Release v7.xx and Subsequent

A feature in the Setup Mode allows Pump mode occlusion pressure to be locked at 10 psi or 517 mmHg (v8.13 only) for all rates.

Hold setup (VOLUME INFUSED) key at power on to enter setup mode.

Instrument SETUP mode

Setup mode defaults

tamper resistant	disabled
P/C mode	unlocked
10 psi mode or517 mmHg (v8.13 only)	disabled
macro/micro mode	MIC/MAC
Primary switchover alert mode	enabled
communications setup:	
serial #	0000
baudrate	9600
parity	off
stopbits	1
accumulated Air In Line Section (V8.xx only)	disabled
language selection	english

1. Press and hold the SETUP control, then press POWER ON
   - Following self test, "Setup PC-1 V7.xx Press Setup Control" scrolls continuously (7.xx identifies installed software release).
2. Press SETUP control - "tamper-resistant mode" scrolls continuously.
   - Press START - "enabled" or "disabled" displays statically.
   - Use the ⇧ or ⇩ controls to select either "enabled" or "disabled" setting
3. Press SETUP control - "P/C mode" scrolls continuously
   - Press START - "locked" or "unlocked" displays statically on the Operator Information display.
   - Selected Delivery mode indicator illuminates.
   - Use the ⇧ or ⇩ controls to toggle between PUMP and CONTROLLER mode.
   - Use the ⇧ or ⇩ controls to select either "unlocked" or "locked" setting.
4. Press SETUP control - "10 psi mode" or "517 mmHg" (v8.13 only) scrolls continuously
   - Press START - "enabled" or "disabled" displays statically.
   - Use the ⇧ or ⇩ controls to select either enabled or disabled setting.
5. Press SETUP control - "macro/micro mode" scrolls continuously
   - Press START - "macro", "micro" or "MIC/MAC" displays statically.

- Use the ⇧ or ⇩ controls to select either "macro", "micro" or "MIC/MAC".

6. Press SETUP control - "Primary switchover alert mode" scrolls continuously
   - Press START - "enabled" or "disabled" displays statically.
   - Use the ⇧ or ⇩ controls to select either "enabled" or "disabled".
7. Press SETUP control - "communications setup" scrolls continuously
   - Press START - "serial #" displays statically.
   - Use 1, 10, 100 and/or CLEAR/SILENCE controls to input serial number.
   - Press PAUSE/STOP - "baudrate" displays statically.
   - Use the ⇧ or ⇩ controls to select baudrate (110, 300, 600, 1200, 2400, 4800 or 9600).
   - Press PAUSE/STOP - "parity" displays statically.
   - Use the ⇧ or ⇩ controls to select parity option (O [odd], E [even] or OFF)
   - Press PAUSE/STOP - "stopbits" displays statically.
   - Use the ⇧ or ⇩ controls to select stop bit option (1 or 2).
8. Press SETUP control - "LANGUAGE SELECTION" scrolls continuously
   - Press START - currently selected language displays statically.
   - Use the ⇧ or ⇩ controls to select language option (english, german, french, italian, swedish, spanish).
9. Press SETUP control - "POWERDOWN" scrolls continuously
   - Press START or PAUSE/STOP controls to power down

   or
10. Press SETUP control - "EXIT SETUP" scrolls continuously
    - Press START to exit setup and enter infusion Setup and Operation mode

      or
    - Press SETUP control to return to "tamper-resistant mode" option.

NOTE

P/C Mode, MICRO or MACRO and 10 psi/ 517 Hg (v8.13 only) modes can be locked/unlocked independent of the SETUP mode.

3.3.1.2 VersaTaper®/AutoTaper® Mode Operation

Fractional Keypad/Series v5.xx/6.xx Software

VersaTaper Setup

1. Ensure the PC-1 pump/controller is turned off.
2. Press the POWER ON control while pressing and holding the VTBI control.
3. When initialization is complete, release the VTBI control and check:
   - Following display of the "PC-1 Vx.xx" message, "VERSATAPER: SETUP" will scroll.
   - Delivery mode/operating indicator will illuminate corresponding to the last delivery mode selected.
   - Rate and VTBI displays will show the last confirmed rate and VTBI for VersaTaper Step 01.
   - "MACRO" or "MICRO" will scroll if the instrument is locked in either mode or if Step 01 contains an integer or fractional value respectfully.
   - If the Step 01 rate and VTBI displays show "0", the "SET RATE" message will scroll and audio prompt will sound.
4. Use the P/C MODE control to select the delivery mode (selection not available if P/C Mode lockout is invoked).
5. Press RATE control:
   - "SET RATE" message will scroll
   - Last confirmed rate will flash in rate display.
6. Use data entry controls to program rate for STEP:01
   - Entered rate will flash in rate display.
   - "STEP:01" will display statically on Operator Information display.
7. Press the VTBI control:
   - Last confirmed VTBI value will flash in the VTBI display.
   - If VTBI value=0, "SET VTBI" message will scroll.
8. Use data entry controls to program VTBI for STEP:01.
9. Press the START control:
   - "STEP:02" will display statically on the Operator Information display.

10. Repeat steps 5 through 9 for each of the VersaTaper Steps to be programmed.

11. After all Steps are programmed, press PAUSE/STOP once:
    - All STEP parameters will be confirmed.
    - Step 01 rate and VTBI values will display.
    - VersaTaper summary message will scroll "STEPS:xx, TOTAL VOL:xxxx, DURATION:hh:mm."

12. Press START control to sequence through the programmed steps to view and/or change any step parameters. To change a parameter use steps 5 through 8, as appropriate.

NOTE

To clear the current and all subsequent steps press the RATE control followed by CLEAR/SILENCE to clear rate(s). Press the VTBI control followed by CLEAR/SILENCE to clear VTBI(s).

13. Press PAUSE/STOP twice to power down the instrument.
    - The VersaTaper infusion is stored and ready to operate when the PC-1 pump/controller is powered up.
    - If the instrument is powered down with all the VersaTaper steps set to Rate = 0 and VTBI = 0, the instrument will initialize in a non-VersaTaper mode when powered up.

VersaTaper Operation

1. Prepare the Primary Infusion as described in Section 3.3.1.1.

2. Press the POWER ON control and check:
    - Normal initialization cycle is completed.
    - "VERSATAPER" message scrolls.
    - Step 01 rate and VTBI appear in the respective displays.
    - VersaTaper report message will scroll "STEP:01" and "TIME LEFT:hh:mm".
    - "PRESS START" message will scroll and audio prompt will sound.

3. If desired, press VOLUME INFUSED and CLEAR/SILENCE controls to reset Total Volume Infused to "0".

4. Press and hold the P/C MODE control for at least one second, then release and press the START control:
    - VersaTaper infusion will begin.
    - Rate for current step will display.
    - VTBI for current step will decrement.
    - "STEP:xx", "TIME LEFT:hh:mm" will scroll continuously throughout the VersaTaper infusion.
    - Total Volume Infused will increment (press VOLUME INFUSED to view).

Software Release V6.xx and Subsequent

The STEP 01 Rate and VTBI will display "0"s until the P/C MODE control is pressed and held for the required one second.

During VersaTaper Infusion

Press RATE control to view each of the remaining VersaTaper steps in sequence (no changes can be entered). The display will revert to the current step ≈6 seconds after last press of RATE control. VTBI control can be pressed to cancel step viewing.

Upon Completion of VersaTaper Infusion

- Audio prompt sounds.
- "INFUSION COMPLETE - KVO" or "EMPTY CONTAINER - KVO" advisory scrolls.
- A KVO infusion is initiated.

To Exit VersaTaper Mode

1. Press the PAUSE/STOP control twice to power down the instrument.

2. Press and hold the CLEAR/SILENCE control while actuating the POWER ON control.

3. The PC-1 pump/controller will initialize in the normal infusion mode.

Titration Keypad/Series v7.xx & Sub. Software

To Enter the VersaTaper or AutoTaper Mode

1. Confirm that the PC-1 is powered off.
2. Press the POWER ON control while simultaneously pressing and holding the VTBI control.
    - "888.8" will show in both displays.
    - "PC-1 Vx.xx" scrolls once across the operator information display.
3. Release the VTBI control when the audio tone has sounded and "888.8" no longer shows in both displays.
    - "VersaTaper: Setup" will scroll.

NOTE

If "VersaTaper: Setup" does not scroll; repeat steps 1-3.

- To activate VersaTaper Setup - press START.

Press VTBI to select "AutoTaper: Ramp Time"
- "AutoTaper: Ramp Time" scrolls on the operator information display.
- To activate "AutoTaper: Ramp Time" - press START.

Press VTBI again to select "AutoTaper: Setup"

- "AutoTaper: Setup" scrolls on the operator information display.
- To activate "Auto Taper: Setup" - press START.

Press VTBI again to select "AutoTaper: Patient"
- "AutoTaper: Patient" scrolls on the operator information display.
- To activate "AutoTaper: Patient" - press START.

Press VTBI once again to select Powerdown
- "Powerdown" scrolls on the operator information display.
- Press START to power down.

NOTE

VTBI control may be pressed again to return to VersaTaper: Setup.

NOTE

Controller delivery mode and empty container detector operation are not available for use in VersaTaper, AutoTaper and AutoTaper Patient modes.

VERSATAPER MODE

To Set Up a VersaTaper Infusion

1. Follow instructions listed above under **To Enter VersaTaper or AutoTaper Mode** and press START to enter VersaTaper: Setup
   - The Pump delivery mode indicator illuminates.
   - Previously entered parameters for STEP 01 will display.
   - "VERSATAPER: SETUP" will scroll.
   - "MACRO" or "MICRO" will scroll if STEP 01 parameters were entered in a previous program.
   - "10 PSI" or "517 mmHg" will scroll if locked in.
2. Press the RATE control and set the desired rate for VersaTaper STEP 01.
   - The "STEP: 01" advisory will display.
3. Press the VTBI control and set the desired VTBI for VersaTaper STEP 01.
4. Press the START control.
   - The "STEP: 01" advisory will be replaced by "STEP: 02" and previously programmed parameters for STEP 02 will display. (If STEP 02 was not previously programmed, zeros will display.)
5. Repeat instructions 2, 3, and 4 to program VersaTaper STEP 02. At the end of instruction 4, the "STEP: 02" advisory will be replaced by "STEP: 03".
6. Repeat this cycle to program VersaTaper STEPS 03 through 20, as required.
7. Press PAUSE/STOP once to enter all programmed VersaTaper parameters.
   - STEP 01 rate and VTBI parameters will display.
   - The following advisories will scroll:
     a. "STEPS: (number of STEPS programmed)".
     b. "TOTAL VOL: (total VTBI for all STEPS programmed)".
     c. "DURATION: (total time in hours and minutes to complete all STEPS programmed)".

   If desired, press START to view each of the programmed VersaTaper STEP parameters in sequence. VersaTaper STEP parameters can also be changed, if required, following instructions 2, 3, and 4.

NOTE

To clear all parameters of the viewed STEP and all subsequent STEPS to "0", press RATE, CLEAR/SILENCE, VTBI, CLEAR/SILENCE, and START.

8. Press PAUSE/STOP a second time to power off the instrument. The VersaTaper infusion is programmed and ready for operation when the instrument comes up in VersaTaper Mode at next power on. If the instrument is powered off after clearing all STEP parameters to zero, then the instrument will initialize in the normal infusion mode at next power on.

To Operate a VersaTaper Infusion

1. Prepare the Primary infusion as described in the non-VersaTaper Mode setup section.
2. Press the POWER ON control.
   - "888.8" will show in both displays and "PC-1 Vx.xx" scrolls once.
   - Audio tone sounds once.
   - "- - - -" appears in the rate and VTBI displays.
   - The "VERSATAPER" advisory will scroll.
3. If desired, press VOLUME INFUSED and CLEAR/SILENCE to clear the Total Volume Infused to "0" before beginning the VersaTaper infusion.
4. Press and hold the P/C MODE control for at least one second.
   - STEP 01 rate and VTBI parameters will display.
   - "STEP: 01" and "TIME LEFT: xx:xx" will scroll.
   - The "PRESS START" prompt will scroll and an audio tone will begin to sound.
5. Press the START control.
   - The instrument will begin the VersaTaper infusion with STEP 01, and will continue through the STEPS of the program until the last STEP is completed.
   - The rate of the active STEP will display.
   - The VTBI of the active STEP will decrement.
   - "STEP: xx TIME LEFT: xx:xx VERSATAPER" will scroll continuously throughout the VersaTaper infusion.
   - The total volume infused increments as the programmed VersaTaper STEPS infuse in sequence. (Press VOLUME INFUSED to view.)

NOTE

During the VersaTaper infusion, press RATE to view each of the programmed STEP parameters in sequence. (No changes can be made.) The display will automatically revert to the current STEP number and will display STEP parameters after approximately 6 seconds, or press VTBI to cancel the viewing.

Upon completion of the infusion:

- An audio prompt sounds.
- An "INFUSION COMPLETE - KVO" or "EMPTY CONTAINER - KVO" advisory scrolls.
- A KVO infusion is initiated and shown in the RATE display.
- A VersaTaper infusion may not be restarted from the KVO state.

To Stop a VersaTaper Infusion

1. Press PAUSE/STOP control twice:
   - "OFF 3" displays; "3" decrements to "1" and then the instrument powers down.

To Resume a VersaTaper Infusion

1. Press POWER ON control to power on the instrument:
   - Following initialization "VERSATAPER" will scroll.
   - The RATE and VTBI displays will show "- - - - ".
   - The operating indicator for the last selected delivery mode will illuminate.
2. Press P/C MODE control for 1 second:
   - The rate and VTBI for the last active Step will appear in the RATE and VTBI displays.
   - "CONTINUE PREVIOUS INFUSION? ↑ = YES ↓ = NO STEP xx TIME LEFT xx:xx VERSATAPER" will scroll.
   - After 30 seconds, Audio prompt will sound.

   a. Press ⏎ to continue the previous infusion:
      - "YES" will appear in the VTBI display.
      - "PRESS START" will scroll.
      - After 30 seconds, audio prompt will sound.

   b. Press START control twice:
      - Previous infusion will resume from the point it was stopped.
      - "STEP: xx TIME LEFT: xx:xx VERSATAPTER" will scroll.
      - Pump mode operating indicator will flash

      or

   c. Press ⏎ to reset the instrument to the beginning of the programmed VersaTaper infusion:
      - "NO" will appear in the VTBI display.
      - "PRESS START" will scroll.

   d. Press START control twice to begin a new VersaTaper infusion:
      - "STEP: xx TIME LEFT: xx:xx VERSATAPER" will scroll.
      - RATE and VTBI displays will show the rate and VTBI for Step 01.
      - The pump mode operating indicator will flash.

AUTOTAPER MODE (must be entered from VersaTaper: Setup using VTBI key)

To Select AutoTaper Ramp Time

1. Press START:
   - "ramp xx%" displays statically (xx = either the last selected ramp % or the default value of 8%).

- Use the ⇧ or ⇩ to increment or decrement ramp (%) between 6% minimum and 12% maximum.

To Setup an AutoTaper Infusion

1. Press VTBI control once:
   - "AutoTaper: Setup" scrolls.
2. Press START:
   - "SET VTBI" and "AUTOTAPER: SETUP" scroll.
   - "- - - -" appears in the VTBI display.
   - The PUMP delivery mode indicator illuminates.
3. Press the VTBI control:
   - Last selected VTBI or "0" flashes in the VTBI display.
   - Use the data entry controls to set the VTBI (between 200 mL minimum and 7896 mL maximum).
4. Press START:
   - Entered VTBI value displays steadily.
   - "SET DURATION" scrolls.
   - Last selected time factor "xx:xx" displays statically alternating with the scrolled message.
   - Use the "1", "10" and CLEAR/SILENCE controls to set delivery time (between 1 and 24 hours).
5. Press START:
   - AutoTaper summary message scrolls "DURATION: xx:xx MAX RATE: xxx RAMP %: xx".

NOTE

Entry of a volume/time parameter that results in a maximum rate >350 mL/hr will cause the "VOLUME/TIME ERROR: SET VTBI" message to scroll

6. Press PAUSE/STOP control once to power down:
   - "OFF 3" displays; "3" decrements to "1" and then the instrument powers down.

To Operate an AutoTaper infusion

1. Prepare the infusion as described in the Primary infusion setup section.
2. Press POWER ON to initialize the instrument:
   - "888.8" will display in both displays and "PC-1 v7.xx or subsequent" scrolls once.
   - Audio tone sounds once.
   - PUMP delivery mode indicator illuminates.
   - "- - - -" appears in both the RATE and VTBI displays.
   - "AUTOTAPER" scrolls.
3. Press the P/C mode control to enable the START control for the AutoTaper infusion.
4. Press the START control:
   - RATE display dynamically shows the rate value for that increment of the ramp currently being envoked.
   - VTBI display shows the total volume to be infused.
   - "TIME LEFT: xx:xx AUTOTAPER" scroll continuously (the time display is dynamic and displays the actual time remaining).
   - The delivery mode operating indicator flashes to confirm the infusion is in progress.

To Stop an AutoTaper Infusion

1. Press PAUSE/STOP control twice:
   - "OFF 3" displays; "3" decrements to "1" and then the instrument powers down.

To Resume an AutoTaper Infusion

1. Press POWER ON control to power on the instrument:
   - Following initialization, "AUTOTAPER" scrolls.
   - RATE and VTBI displays show "- - - -".
   - Delivery mode operating indicator for the previously selected delivery mode illuminates.
2. Press and hold P/C MODE control for 1 second:
   - The rate and the volume remaining to be infused when the infusion was stopped will appear in the RATE and VTBI displays.
   - "CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑ = YES ↓ = NO AUTOTAPER" will scroll.
   - After 30 seconds, audio prompt will begin.

   a. Press ⇧ to continue the previous infusion:
      - "YES" will appear in the VTBI display.
      - "PRESS START" will scroll.
      - "CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑ = YES ↓ = NO" will scroll.
      - After 30 seconds, audio prompt will begin.

   b. Press START control twice:
      - Previous infusion will resume from the point it was stopped.
      - "TIME LEFT: xx:xx AUTOTAPER" will scroll.
      - Delivery mode operating indicator will flash

   or

   c. Press ⇩ to reset the instrument to the beginning of the infusion:
      - "NO" will appear in the VTBI display.
      - "PRESS START" will scroll.
      - "CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑ = YES ↓ = NO" will scroll.

d. Press START control once:
- "TIME LEFT: xx:xx PRESS START AUTOTAPER" will scroll.
- VTBI display will show the programmed VTBI .
- After 30 seconds, audio prompt will sound.

e. Press START control again to start infusion:
- "TIME LEFT: xx:xx AUTOTAPER" will scroll.
- RATE display will show the current operating rate.
- VTBI display will show the programmed volume to be infused.
- The pump mode operating indicator will flash.

To Enable an AutoTaper: Patient infusion

1. Following initialization in the VersaTaper and AutoTaper setup mode, press the VTBI control until "AutoTaper: Patient" scrolls on the operator information display.
2. Press START control:
   - "enabled" or "disabled" will appear statically on the operator information display.
   - The delivery mode operating indicator for the last selected delivery mode will illuminate.
3. Use the ⇧ or ⇩ controls to select "enabled", if necessary.
4. Press VTBI control to select "Powerdown".
5. Press START to power down the instrument.

To Set Up and Operate an AutoTaper Patient Infusion

1. Press POWER ON to power up the instrument (AutoTaper: Patient mode must be enabled):
   - "AUTOTAPER: PATIENT" scrolls.
   - RATE and VTBI displays show " - - - - ".
   - The Pump delivery mode indicator illuminates.
2. Press and hold the P/C MODE control for 1 second:
   - "SET VTBI" scrolls.
   - RATE display is blank.
   - VTBI display shows " - - - - ".
   - After 30 seconds, audio prompt sounds.
3. Press VTBI control:
   - Last selected VTBI or "0" flash in the VTBI display.
   - After 30 seconds, audio prompt sounds.
   - Use data entry controls to set VTBI.
4. Press START control:
   - Selected VTBI value displays steadily.
   - "SET DURATION" scrolls.
   - "xx:xx" displays statically alternating with scrolled message(s).
   - Use "10" or "1" data entry controls to set duration.
5. Press START control:
   - "DURATION: xx:xx MAX RATE: xxx RAMP %: XX" and "PRESS START" scroll.
   - After 30 seconds, audio prompt sounds.

NOTE

Entry of a volume/time parameter that results in a maximum rate >350 mL/hr will cause the "VOLUME/TIME ERROR: SET VTBI" message to scroll.

6. Press START control again to start infusion:
   - "TIME LEFT: xx:xx AUTOTAPER" scrolls.
   - RATE display shows active delivery rate.
   - VTBI display shows volume to be infused.
   - The pump delivery mode indicator flashes.

To Stop an AutoTaper Patient Infusion

1. Press PAUSE/STOP twice:
   - "OFF 3" displays; "3" decrements to "1" and then the instrument powers down.

To Resume an AutoTaper Patient Infusion

1. Press POWER ON control to power on the instrument:
   - Following initialization, "AUTOTAPER: PATIENT" scrolls..
   - RATE and VTBI displays show " - - - - ".
   - The pump delivery mode indicator illuminates.
2. Press and hold P/C MODE control for 1 second:
   - The active rate and the volume remaining to be infused when the infusion was stopped will appear in the RATE and VTBI displays.
   - "CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑ = YES ↓ = NO AUTOTAPER" will scroll.
   - After 30 seconds, audio prompt will begin.

   a. Press ⇧ to continue the previous infusion:
      - "YES" will appear in the VTBI display.
      - "PRESS START" will scroll.
      - "CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑ = YES ↓ = NO" will scroll.
      - After 30 seconds, audio prompt will begin.

   b. Press START control:
      - RATE and VTBI displays will show parameters active when infusion was stopped.
      - "TIME LEFT: xx:xx PRESS START AUTOTAPTER" will scroll.
      - After 30 seconds, audio prompt will sound.

c. Press START to resume previous autotaper infusion:
   - The pump delivery mode operating indicator will flash.
   - "TIME LEFT xx:xx AUTOTAPER" will scroll

   or

d. Press ⟲ to reset the instrument to the beginning of the infusion.
   - "NO" will appear in the VTBI display.
   - "PRESS START" will scroll.
   - "CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑ = YES ↓ = NO" will scroll.
   - After 30 seconds, audio prompt will sound.

e. Press START control once:
   - "SET VTBI" will scroll.
   - RATE display will be blank.
   - VTBI display will show " - - - - ".
   - After 30 seconds, audio prompt will sound.

3. Follow steps 3-6 in Section: **To setup and operate an AutoTaper Patient infusion.**

To Exit the VersaTaper/AutoTaper Mode

1. Press the PAUSE/STOP control twice, which will power off the instrument.
2. Press the POWER ON control while simultaneously pressing and holding the CLEAR/SILENCE control until an audio tone has sounded.
3. The PC-1 may now be operated as described in the normal infusion mode sections of this manual.

3.3.1.3 Battery Powered Operation

The PC-1 pump/controller will provide normal operation under battery power for a limited period of time for ambulatory use or as a backup to primary power in the event of a power interruption. Battery operating life can be extended by utilizing delivery rates with low motor current draw. The following procedures are recommended for battery powered operation:

1. A new fully-charged battery will provide 5 hours of instrument operation (delivery rate of 125 mL/hr).

NOTE

From a HELP BATTERY condition, recharging requires 4 hours with the instrument off, or 18 hours with the instrument operating at 125 mL/hr.

Any time a LOW BATTERY advisory is displayed, the battery should be fully recharged prior to subsequent battery powered instrument operation.

2. Configure the pump for operation in the same manner as for normal operation (see paragraph 3.3.1.1).

3. Actuate the POWER ON Control. All indicators and displays will react as in normal operation (see paragraph 3.3.1.1 e), except the Battery Operation Indicator will remain on.

4. Install administration set in the pump.

5. Set Delivery Mode, Rate and VTBI in the same manner as for normal operation.

6. Press START Control. Battery operation indicator will flash.

CAUTION

Instruments that have not been operated for a period of 30 days must be plugged in and charged for 24 hours prior to use.

Software Release V6.xx and Subsequent

- When AC power is removed, instrument will not sound changeover audio
- Battery Operation indicator will flash during battery operation
- "ON BATT" will scroll twice every 30 seconds during battery operation **[v6.45 ONLY]**
- During battery operation, Operator Information Display will be dimmed; at Low Battery, display brightness will be further dimmed.
- At Low Battery, Rate and VTBI displays will flash.

Software Release V6.3x and Subsequent

When the instrument is disconnected from AC power while operating or powered up on battery, an elapsed time counter will initiate and after 5 hours will signal a Timed Low Battery condition:

- "LOW BATTERY..." will scroll.
- Audio prompt will sound.
- Reconnecting AC power will cause time counter to decrement at the same rate.
- Voltage threshold Low Battery will override Timed Low Battery.

3.3.2 Maintenance/Diagnostic Mode

The Maintenance/Diagnostic Mode is incorporated into the PC-1 pump/controller to provide biomedical personnel access to the diagnostic test routines. Entry into the Maintenance Mode is accomplished by performing the following procedure:

1. Press and hold the COMPUTER CONTROL/ MONITOR switch while actuating the POWER ON control to initialize the instrument.
   - Assure all indicators illuminate, all segments of the RATE and VTBI displays illuminate ("888.8"); the operator information display remains blank.
   - "PC-1 Vx.xx" scrolls once across the operator information display (x.xx represents the installed software version).

   Software Release v2.xx through v6.xx
   - "maintenance Vx.xx To Exit Press STOP" message scrolls continuously.

   Software Release v7.xx and Subsequent
   - "Diagnostics V7.xx To Exit Press <stop>" message scrolls continuously
   - Keyclick audio sounds once.

2. Each actuation of the COMPUTER CONTROL/ MONITOR switch will sequentially step control from one test to the next in the following sequence:

Software Release V2.xx and V5.xx
- Lamp Test with Audio
- Keypad Test
- Error Log Display
- Motor Homing Test
- Pump Test
- Serial Port Tests
- A/D Voltage Display
- Input Port Display
- Communications Setup
- Language
- Powerdown Test

Software Release V5.59 & V6.xx
- Error Log Display
- Pump Test
- A/D Voltage Test
- Input Port Display
- Communications Setup
- Serial Port Test
- Language Selection

Software Release v7.xx and Subsequent
- Error Log Display
- Pump Test
- Motor Homing Test
- A/D Voltage Test
- Input Port Display
- Lamp Test
- Keypad Test
- Communications Setup
- Serial Port Test
- ROM CRC Display
- ROM Checksum Display (V7.xx only)
- Battery Data Display
- Audio Test
- Powerdown Test

Each of these tests, when selected, is accompanied by a scrolled confirmation message on the Operator Information Display.

3. Each test is initiated by actuating the START control. The scrolled test identifier is replaced with a statically displayed test phase identifier. The PAUSE/STOP control is used to change test phases within a test routine. Exiting from a subroutine loop is accomplished by actuating the COMPUTER CONTROL/ MONITOR switch which selects the next test in the above listed test sequence. Detailed test procedures are found in Section 5 of this manual.

4. **Software Releases v2.xx through v5.xx**
   Actuation of the PAUSE/STOP control while a test identifier is scrolling will interrupt the test sequence, skip the remaining tests and go to the powerdown test.

   Software Release v6.xx ONLY
   The Maintenance Mode can only be exited when the "Maintenance V6.xx To exit press "stop" message is scrolling by pressing the PAUSE/STOP control.

   Software Release v7.xx and Subsequent
   The Powerdown Test must be selected and START control pressed to exit the Diagnostic mode.

3.4 OPERATOR INFORMATION DISPLAY AND ALARM RESPONSE PROCEDURES

In the normal operating mode, four types of visual displays are presented to the operator: prompts, advisories, alarms and malfunctions. Under certain conditions, it is possible for one or more types of messages to be active at the same time. Should this situation occur, the messages will be sequenced such that each message will display once before any message is repeated. The display of "Volume Infused" will take precedence over prompts and advisories, but not over alarm or malfunction messages.

Table 3-2 lists the Status/Alarm Displays presented by the PC-1 pump/controller, identifies the probable cause and defines the recommended operator response.

The PC-1 Visual Indicator Displays are characterized as follows:

RATE and VTBI Displays

Type	Presentation
1	0.5 sec flash
2	Steady

STATUS/ALARM Display

3	Scroll
4	Interrupted Scroll (Sensor initiated message takes precedence over Prompt)
5	Static (Applicable ONLY in the maintenance and VersaTaper modes)

3.5 AUDIO ALERT SYSTEM

The PC-1 pump/controller is programmed to produce six distinct audio alerts. The attributes of each are described in Figure 1-2.

Table 3-2. PC-1 pump/controller Status/Alarm Displays

Condition/Display	Cause	Response
PROMPTS		
A Prompt is a visual alert requesting the instrument operator to take a specific action.		
PRESS START Audio - Prompt Visual - continuous scroll	Initiates following actuation of the latter of RATE and VTBI in conjunction with programming an infusion, or 12 seconds after an alarm is cleared, or 2 minutes after PAUSE is selected.	Press START Control.
SET RATE Audio - Prompt Visual - continuous scroll	Follows actuation of RATE control, or if START is pressed with rate set to "0".	Press RATE and set rate to a non-zero value.
SELECT P/C MODE Audio - none Visual - scrolls once	Follows initialization sequence during instrument power up, if P/C Mode is not locked out.	Select Pump or Controller Mode.
SET VTBI Audio - Prompt Visual - continuous scroll	Follows actuation of VTBI control, or if START is pressed with VTBI set to "0".	Press VTBI control and set VTBI to a non-zero value.
ADVISORIES		
An Advisory is a visual and audio alert to the instrument operator that an extraordinary, but non-critical condition exists, and operator action should be taken as soon as possible.		
SECONDARY Audio - (6 beeps when complete, when enabled) Visual - continuous scroll	Secondary infusion in progress.	None.
PRIMARY Audio - none Visual - continuous scroll	SEC/Piggyback control actuated while operating in Secondary and after changeover from secondary to primary infusion.	None.
INFUSION COMPLETE - KVO Audio - Prompt Visual - continuous scroll	Programmed VTBI reaches 0, **(All except PC-1 CE - V8.xx 220V)** or an ALL infusion complete using ECD.	Press PAUSE/STOP control twice or set up another infusion.
All except PC-1CE - V8.xx 220V EMPTY CONTAINER - KVO Audio - Prompt Visual - continuous scroll	Empty container detected by ECD before programmed VTBI delivered, or when ALL infusion is used.	Press PAUSE/ STOP control twice or set up another infusion.
LOW BATTERY Audio - Prompt Visual - continuous scroll	5.8 ±0.1V threshold detected; ≈0.5 hour battery operating time remaining.	Connect AC power cord to outlet.

Table 3-2 (cont.). PC-1 Pump/Controller Status/Alarm Displays

Condition/Display	Cause	Response
ADVISORIES (cont)		
PAUSE Audio - Advisory (immediately), Prompt (after 2 minutes) Visual - continuous scroll	PAUSE/STOP Control pressed once.	Press START to resume infusion, or press PAUSE/STOP again to shut down instrument.
MAINTENANCE **[v2.xx/5.xx/6.xx]** Audio - beeps once Visual - continuous scroll	COMPUTER CONTROL/MONITOR switch pressed and held during Power On sequence.	**DO NOT USE ON PATIENT.** For use by biomedical technician only.
DIAGNOSTIC **[v7.xx and subsequent]** Audio - beeps once Visual - continuous scroll	COMPUTER CONTROL/MONITOR switch pressed and held during Power On sequence.	**DO NOT USE ON PATIENT.** For use by biomedical technician only.
LOW FLOW Audio - Advisory Visual - continuous scroll	In Controller mode, distal tubing in-line pressure equals bottle height resulting in no flow.	Remedy cause of Low Flow condition or raise IV bottle.
TOTAL VOL INFUSED Audio - none Visual - single scroll	VOLUME INFUSED control actuated once.	None (Numeric value in VTBI display is cumulative Primary plus Secondary).
SEC VOL INFUSED Audio - none Visual - single scroll	VOLUME INFUSED control actuated twice while in Secondary state.	None (Numeric value in VTBI display is Secondary solution volume ONLY).
<u>Fractional Keypad/Series V5.xx and Subsequent Software</u>		
MICRO Audio - none Visual - scroll	Instrument has been initialized in the MICRO delivery mode.	Fractional rate and VTBI parameters are accepted by the instrument.
MACRO Audio - none Visual - scroll	Instrument has been initialized in the MACRO delivery mode.	Integer rate and VTBI parameters are accepted by the instrument.
VERSATAPER Audio - none Visual - scroll	Instrument is operating in the VersaTaper delivery mode.	None.
VERSATAPER: SETUP Audio - none Visual - scroll	Instrument has been initialized in the VersaTaper Setup mode.	VersaTaper steps 1-20 can be sequentially programmed for rate and VTBI.
STEP:xx Audio - none Visual - static	Identifies the VersaTaper step to be programmed.	Enter rate and VTBI values for the step identified.

Table 3-2 (cont.). PC-1 Pump/Controller Status/Alarm Displays

Condition/Display	Cause	Response
(VersaTaper Summary) - STEPS:xx, TOTAL VOL:xxxx, DURATION:hh:mm Audio - none Visual - continuous scroll	After programming the desired VersaTaper Steps, the PAUSE/ STOP control was actuated to enter and summarize VersaTaper program.	View and edit VersaTaper program as required.
(VersaTaper Report) - STEP:xx, TIME LEFT:hh:mm Audio - none Visual - continuous scroll	Instrument has been powered up in the VersaTaper operate mode.	None - awaiting start of the VersaTaper infusion.
Software Release V6.xx and Subsequent		
10 psi or 517 mmHg (v8.13 only) Audio - none Visual -scrolls until START or - COMPUTER CONTROL/ MONITOR switch is pressed	Pump mode is locked into 10 ±2 psi occlusion detection.	None - Time to occlusion at low rates will be significantly increased.
Software Release V6.2x through V6.4x		
ON BATT Audio - none Visual - flashes twice every 20 seconds	Instrument is operating on battery power.	Connect AC power cord to a suitable AC power source.
Software Release V6.3x and Subsequent		
LOW BATTERY... Audio - Prompt Visual - continuous scroll	Five hours have elapsed since an operating instrument was disconnected from AC power.	Connect the instrument to an AC power source.
Software Release v7.xx and Subsequent		
CONTINUE PREVIOUS INFUSION? ↑=YES ↓=NO STEP: xx TIME LEFT: xx:xx VERSATAPER Audio: none Visual: continuous scroll	VersaTaper infusion has been reentered after an incompleted prior infusion.	Use the ⇧ or ⇩ controls to continue or discontinue previous infusion.
CONTINUE PREVIOUS INFUSION? ↑=YES ↓=NO Audio: none Visual: continuous scroll	The Yes option to continue the previous infusion has been selected.	None. Pressing ⇩ will change the selection from continue to discontinue.
yes Audio: none Visual: static display	The Yes option to continue the previous AutoTaper/VersaTaper infusion has been selected.	Press START to resume previous infusion.
no Audio: none Visual: static display	The No option to discontinue the previous AutoTaper/VersaTaper infusion has been selected.	Press START to begin a new infusion.

Table 3-2 (cont.). PC-1 Pump/Controller Status/Alarm Displays

Condition/Display	Cause	Response
ADVISORIES (cont)		
AutoTaper: Ramp Time Audio: none Visual: continuous scroll	AutoTaper Ramp Time setup mode has been selected.	Press START to enable ramp time (%) selection.
ramp% xx Audio: none Visual: static display	AutoTaper ramp% selection mode is enabled.	Use ⇧ or ⇩ to select ramp % (between 6 and 12%, default setting 8%).
AutoTaper: Setup Audio: none Visual: continuous scroll	AutoTaper setup mode has been selected.	Press START to enable selection of AutoTaper infusion parameters.
AUTOTAPER: SETUP Audio: none Visual: continuous scroll	AutoTaper setup mode has been enabled.	Use infusion parameter entry controls to program AutoTaper infusion.
SET DURATION Audio: none Visual: alternating scroll	AutoTaper setup mode is ready for infusion duration input.	Use "10" and or "1" controls to set duration (between 1 and 24 hours).
DURATION: xx:xx MAX RATE: xxx RAMP %: xx Audio: none Visual: continuous scroll	AutoTaper Setup summary message.	None. Press PAUSE/STOP to exit AutoTaper: Setup.
AUTOTAPER Audio: none Visual: continuous scroll	PC-1 pump/controller is ready or operating in AutoTaper mode.	If in ready condition, press and hold P/C MODE control for 1 second; then press START.
TIME LEFT: xx:xx AUTOTAPER Audio: none Visual: continuous scroll	PC-1 pump/controller is ready or performing an AutoTaper infusion.	None.
CONTINUE LAST xx:xx OF PREVIOUS INFUSION? ↑=YES ↓=NO AUTOTAPER Audio: none Visual: continuous scroll	AutoTaper infusion has been reentered after an incompleted prior infusion.	Use the ⇧ or ⇩ controls to continue or discontinue previous infusion.
AutoTaper: Patient Audio: none Visual: continuous scroll	AutoTaper Patient mode enable has been selected.	Use ⇧ or ⇩ controls to enable or disable AutoTaper Patient infusion mode.
enabled Audio: none Visual: static display	AutoTaper Patient mode has been enabled.	Press VTBI, then START to exit AutoTaper: Patient setup mode.

Table 3-2 (cont.). PC-1 Pump/Controller Status/Alarm Displays

Condition/Display	Cause	Response
ADVISORIES (cont)		
disabled Audio: none Visual: static display	AutoTaper Patient mode has been disabled.	Press VTBI, then START to exit AutoTaper: Patient setup mode.
VOLUME/TIME ERROR: SET VTBI Audio: none Visual: continuous scroll	Volume and/or time input resulted in a max rate >350 mL/hr.	Press VTBI control to re-enter volume and/or time parameter.
ALARMS		
An Alarm condition is signaled by a combined visual and audio alert to the instrument operator that an abnormal situation exists, pumping stops and operator action is required immediately.		
CHECK IV SET Audio - Alarm Visual - continuous scroll	Administration set missing or not properly installed.	Silence alarm, reinstall disposable, press START control.
CLOSE DOOR Audio - Alarm Visual - continuous scroll	Door open while infusing with Flo-Stop in no flow position.	Close and latch door, press START control.
FLO-STOP OPEN/CLOSE DOOR Audio - Alarm Visual - continuous scroll	Pumping chamber access door open and Flo-Stop is in open free flow position.	Close and latch door or close roller clamp on administration set, then silence alarm.
All except PC-1CE V8.xx 220V. CHECK ECD Audio - Alarm Visual - continuous scroll	START control actuated with VTBI set to ALL and ECD has become disconnected or failed.	Silence alarm, connect/repair ECD, or set VTBI to a parameter (not ALL), press START.
AIR IN LINE Audio - Alarm Visual - continuous scroll	AIL sensor activated during infusion or KVO state.	Silence alarm, remove air from set tubing, press START Control.
OCCLUDED-PATIENT SIDE Audio - Alarm Visual - continuous scroll	Elevated backpressure sensed while infusing in the Pump mode.	Silence alarm, Clear occlusion, press START control.
OCCLUDED-FLUID SIDE Audio - Alarm Visual - continuous scroll	Proximal vacuum sensed while infusing in the Pump mode.	Silence alarm, clear occlusion, press START control.
OCCLUDED Audio - Alarm Visual - continuous scroll	In Controller mode when: LOW FLOW condition exists for >60 seconds, catch up time for volumetric deficiency exceeds 30 minutes, or an abrupt increase in distal side pressure exceeds occlusion threshold.	Silence alarm, clear occlusion, press START control.

Table 3-2 (cont.). PC-1 Pump/Controller Status/Alarm Displays

Condition/Display	Cause	Response
ALARMS (continued		
PARTIAL OCCLUSION-FLUID SIDE Audio - Alarm Visual - continuous scroll	Reduced pressure detected in the proximal tubing resulting from partial filling of the pumping chamber while infusing in Pump mode.	Silence alarm, rectify cause of reduced flow, press START.
Software Release V6.xx and Subsequent		
COMM CABLE Audio - alarm Visual - continuous scroll	Communications interface cable is disconnected.	Reconnect communications cable. Press COMPUTER CONTROL/MONITOR switch, PAUSE or START to resume infusion.
COMM TOUT Audio - alarm Visual - continuous scroll	Communications timeout has occurred.	Press COMPUTER CONTROL/ MONITOR switch to change instrument to MONITOR.
KVO Audio - alarm Visual - continuous scroll	Communications cable disconnected or timeout has occurred while infusing. Infusion continues at KVO rate.	Correct problem, press START to resume programmed infusion. Press COMPUTER CONTROL/ MONITOR to return to host computer control.
MALFUNCTIONS		
A Malfunction condition is signaled by an audio alert; pumping stops and an Error Log message is recorded. Software detected malfunctions are accompanied by a visual "HELP" message. No visual messages accompany hardware detected malfunctions. Instruments experiencing hardware malfunctions must be taken out of service and the malfunctions must be corrected by a qualified biomedical technician prior to returning the instrument to service.		
HELP BATTERY Audio - Malfunction Visual - continuous scroll	5.5 ±0.1V threshold detected; pumping stops.	Press PAUSE/STOP to power down the instrument; if unable press POWER ON to interrupt power. Plug AC power cord into an AC power source, then re-initialize the instrument.
HELP INTERNAL ERROR Audio - Malfunction Visual - continuous scroll	Software detected malfunction - system failure, pumping stops.	Press PAUSE/STOP control to shut off electrical power. Replace instrument.
(SYSTEM FAILURE) Audio - Malfunction Visual - None	Hardware detected malfunction, pumping stops.	Press POWER ON Control to reset electrical power. Replace instrument.

SECTION 4 - PRINCIPLES OF OPERATION

4.1 INTRODUCTION

This section describes the functional operation of the mechanical and electrical/electronic subsystems of the GEMINI PC-1® Volumetric Infusion Pump/ Controller ("PC-1"). The material is presented in a manner and format that is complementary to the troubleshooting routines delineated in Section 5 - Maintenance. The technical descriptions are referenced to the electrical schematics, mechanical diagrams and illustrated parts breakdowns presented in sections 4, 5 and 6.

The functional descriptions presented in this section are divided into two subsections. The first addresses the mechanical system operation and the second describes the electrical/electronic control circuits and operational displays. The electrical theory of operation is described in relation to the Functional Block Diagram depicted in figure 4-2, and can be best understood by following the description on the logic diagrams, display board schematic and interconnect diagram.

4.2 MECHANICAL OPERATION

The following material is presented in a manner that assumes the reader has a basic understanding of the information provided in sections 1 through 3 of this manual and in addition has hands-on experience in setting up and operating the PC-1 pump/controller. Direct observation of the mechanical sequence of events that occur during instrument operation is not possible with the pumping mechanism and strain beam installed in the PC-1 pump/controller. However, by reading the following text while referring to the appropriate figures, a thorough understanding of the instrument's mechanical operation can be acquired.

4.2.1 Physical Description

4.2.1.1 Pumping Mechanism

The pumping mechanism assembly consists of three principle subassemblies: the stepper motor, the camshaft/pumping finger housing and the motion sensor (see Figure 4-1). The stepper motor drive shaft is connected to the camshaft by a flexible coupling. The encoder wheel of the motion sensing assembly is connected directly to the top of the camshaft. The camshaft is configured with 12 vertically staged cam lobes. The eccentric axis of each lobe is offset 30° counterclockwise from the lobe directly above. This positioning provides full forward travel for each pumping finger sequentially from top to bottom during each counterclockwise (when viewed from above) revolution of the camshaft. The cam lobes are evenly spaced except numbers 9 and 10 which are separated by 5/8" to accommodate a strain beam type pressure sensor.

4.2.1.2 Strain Beam (Pressure Transducer)

The strain beam assembly consists of the housing assembly, a strain beam and sensing finger (see Figure 4-3). The housing assembly is mounted on the front case assembly behind the urethane pump seal and is positioned between fingers 9 and 10 of the pumping mechanism. Four strain sensitive resistors are deposited on the strain beam, two on the tension section and two on the compression section.

4.2.2 Functional Operation

4.2.2.1 Pumping Mechanism

In the Normal operating mode, the PC-1 pump/controller is initialized when the POWER ON control is actuated. The pumping mechanism begins operating when an administration set is installed, infusion parameters are programmed and the START control is actuated. A stepper motor is directly coupled to a camshaft which actuates the pumping fingers. Stepper motor speed is variable and it is driven at a speed proportional to the rate programmed for the infusion.

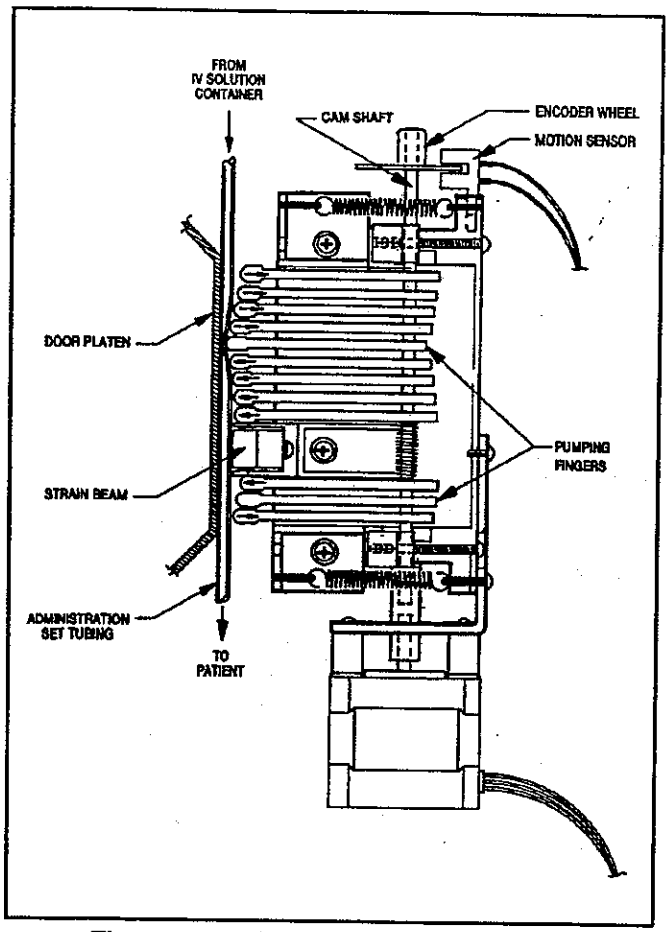


Figure 4-1. PC-1 Pumping Mechanism

Volume to be infused (VTBI) is a function of the total number of steps issued to the motor for a programmed infusion rate. An encoder wheel attached to the camshaft and a motion sensor mounted on the pumping mechanism's top plate assembly provides the electronic control system with camshaft's position, direction and speed of rotation. Encoder wheel position data is fed back to the processor through U6 to verify rate accuracy.

When an administration set is installed in the pumping chamber and the access door is closed and latched, the set's Flo-Stop is opened. The pumping segment tubing is compressed between the fully extended pumping finger and the door platen, thus preventing free flow. The pumping mechanism is started following actuation of the START control when performing normal instrument operating procedures. The stepper motor rotates the camshaft at a speed determined by the programmed infusion rate. Each pump cycle consists of 200 motor steps of 1.8° each. Inter-step timing of the motor is varied as necessary to dampen the inherent non-linearity of peristaltic pumping mechanisms and produce a uniform rate of fluid flow throughout each pumping cycle. The sequential extension and retraction of the pumping fingers from top to bottom results in a downward moving compression zone within the administration set's pumping segment (see Figure 4-1) which creates positive pressure on the outlet side (distal end) of the tubing set. The elastomeric resilience of the pumping segment tubing causes it to return to its cylindrical shape as each of the pumping fingers recede from the extended position. This reshaping creates a vacuum in the proximal tubing and causes fluid from the IV solution container to refill the tubing. This peristaltic-like action results in a constant, controlled flow of IV solution from the container to the patient.

During each pump cycle, between motor steps 62 through 77, the strain beam senses the hydrostatic pressure in the fluid column above the strain beam. In the event there is restricted flow in the tubing between the fluid container and pump and the tubing can not refill completely, the strain beam will sense lower than normal pressure and cause the instrument to enter a LOW FLOW condition when operating in the Controller mode or either a PARTIAL OCCLUSION-FLUID SIDE or OCCLUSION-FLUID SIDE condition when in the Pump mode.

In the Controller mode if the pressure differential between patient and fluid container drops to less than 6 inches (0.22 psi; 1.7 kPa) of water pressure, the pumping mechanism will stop. The microprocessor monitors the duration of a *low flow* condition and then automatically increases the delivery rate, up to a maximum of 10% above the programmed rate. Pumping resumes once the fluid container to patient pressure differential equals or exceeds 12 inches (30.48 cm) [0.43 psi; 3.4 kPa] of water pressure. The increased flow rate allows the instrument to compensate for the period of *low flow* and bring the actual volume infused in line with the programmed infusion parameters. Once the pump has completed this catch-up cycle, the delivery rate reverts to the programmed rate. Should the *low flow* condition persist for more than 1 minute or the calculated time necessary to compensate for the under-infusion condition exceeds 30 minutes, the instrument will enter an Occlusion alarm condition.

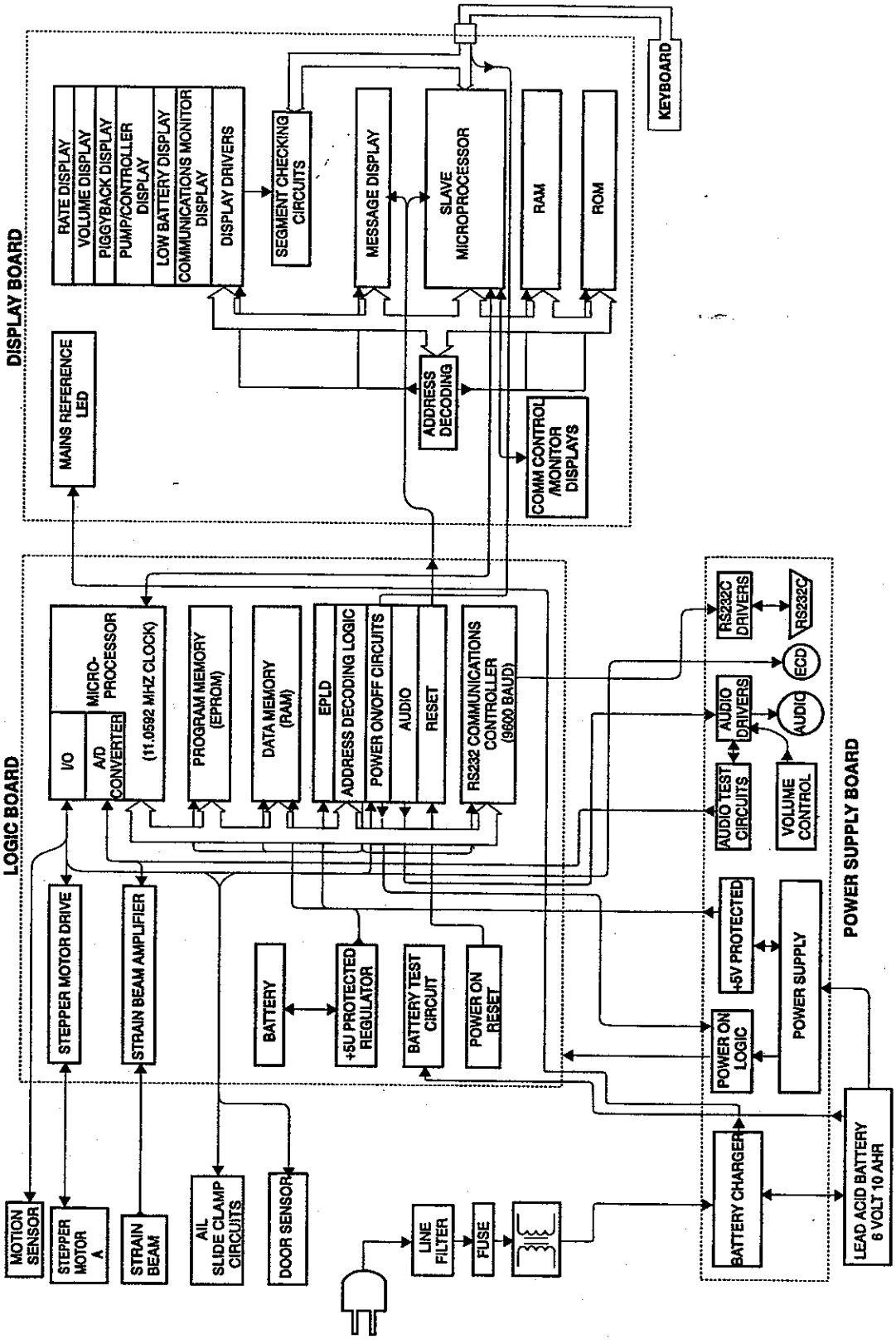


Figure 4-2. Functional Block Diagram [**v2.xx/5.xx/6.xx**]

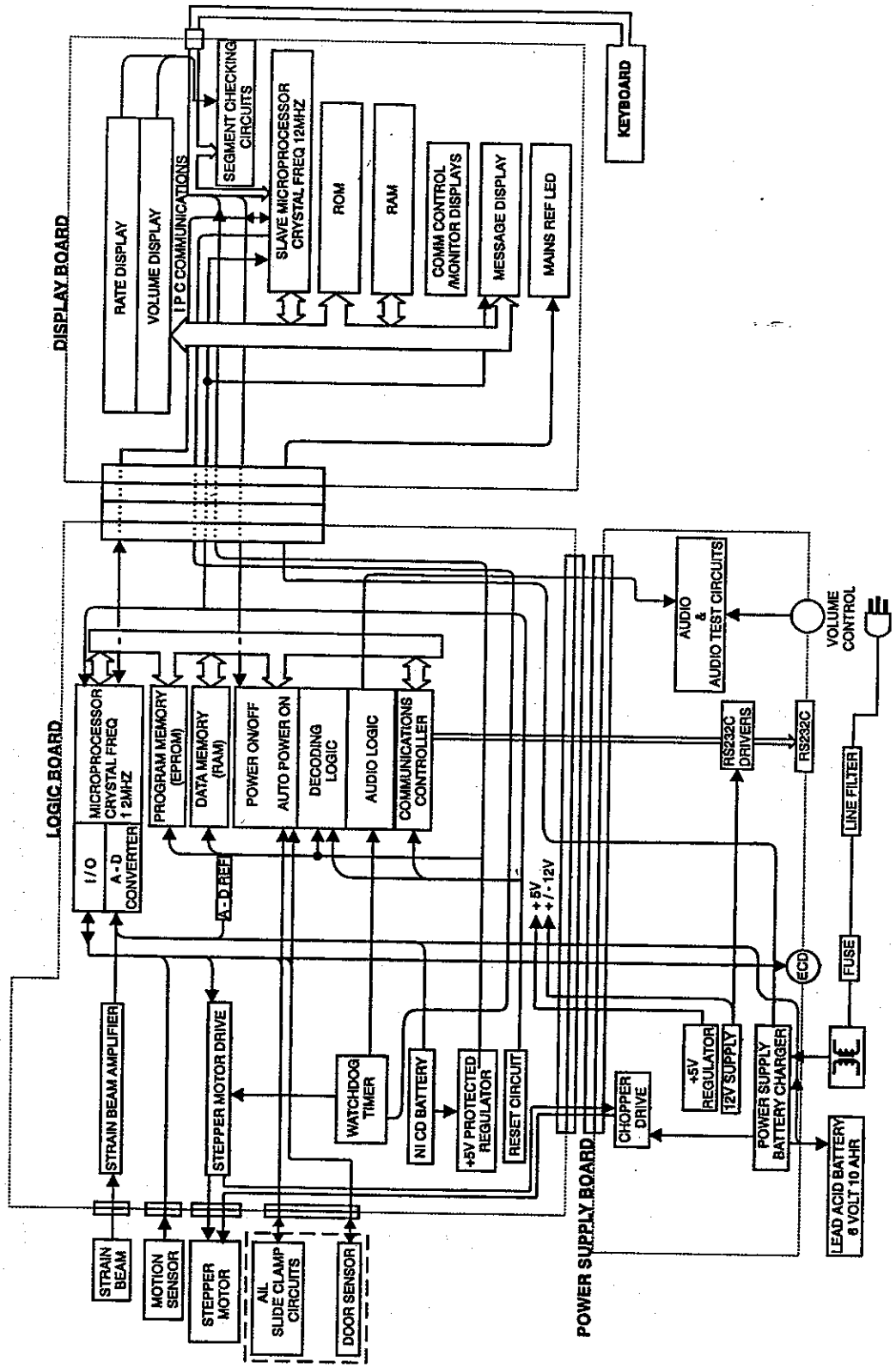


Figure 4-2a. Functional Block Diagram [**v7.xx**]

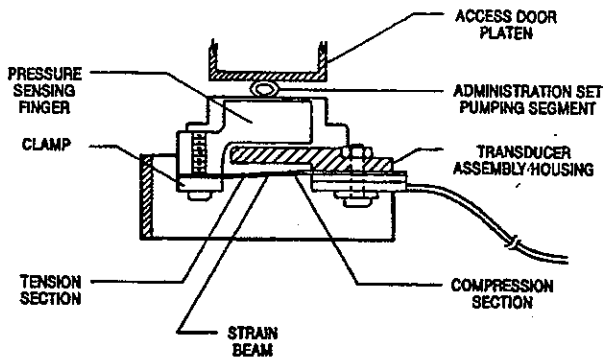


Figure 4-3.Cross Section of Strain Beam Assembly

During each pump cycle, between motor steps 0 through 20 and 120 through 199, the strain beam measures the pressure in the distal tubing. Any restriction to flow in the distal tubing will cause the pressure to increase and the tubing to expand. The strain beam will sense increasing pressure and when a predetermined threshold is exceeded, the instrument will invoke either an OCCLUSION (Controller mode) or an OCCLUSION-PATIENT SIDE (Pump mode) alarm condition. During any alarm condition, the pumping mechanism stops and appropriate audio and visual alerts are issued. (Between motor steps 21-62 and 77-119 pumping finger positioning precludes the strain beam from reading distal or proximal pressure).

4.2.2.2 Strain Beam (Pressure Transducer)

When the pumping segment of a primed administration set is installed in the PC-1 pumping chamber and the access door is closed, the strain beam will sense the pressure in the tubing. Actual pressure values are a function of pumping finger position within a pump cycle and the hydrostatic pressure in the tubing at the time of measurement. Typically strain beam voltage would be in the range of 1 to 3 volts if the strain beam was looking at the patient-side tubing. During pump operation, a positive pressure increase in the fluid column above or below the pump will cause the tubing to expand and result in deflection of the strain beam. This positive deflection will result in an increase in the potential measured across the strain beam's resistor bridge. A decrease in pressure within the tubing set's fluid column will result in contraction of the tubing diameter with a resultant negative deflection of the strain beam and reduction in the potential measured across the bridge circuit.

4.3 ELECTRICAL/ELECTRONIC OPERATION

An understanding of the electrical/electronic theory of operation can be acquired by reading the ensuing subsystem descriptions while following the functional schematic for the respective subsystem.

4.3.1 Functional Description

Integer/Fractional Keypad Instruments

The PC-1's electrical/electronic subsystem is operated and controlled by a logic subsystem employing an Intel 8097BH 16 bit microcontroller with an integral A/D converter. The logic subsystem includes a programmed memory containing the instrument's operating code; a non-volatile memory for retention of programmed infusion parameters, error log storage and general system use; a logic decoder to define memory space, implement ready logic, decode sensor strobes and controls audio. The interaction of the logic subsystem components and instrument hardware is functionally depicted in the Logic Block diagram, Figure 4-2. The electrical interconnection of the instrument's components is shown in Figure 4-4.

The memory accessible by the main processor covers 64K bytes of combined internal RAM and register space which is allocated as follows: 256 bytes to internal microprocessor RAM, 3840 bytes to mapped I/O, 4096 bytes to external RAM (Variable, Stack and NVRAM memory) and 56K bytes to external ROM (Program and Data Memory). Figure 4-23 shows the Microprocessor system interconnection.

A 11.0592 MHz crystal external to the microcontroller provides the master clock signal. The microprocessor timing waveforms are shown in Figure 4-5.

Titration Keypad Instruments

The PC-1's electrical/electronic subsystem is operated and controlled by a logic subsystem employing an Intel 80C196KB 16 bit microcontroller with an integral A/D converter. The logic subsystem includes a programmed memory containing

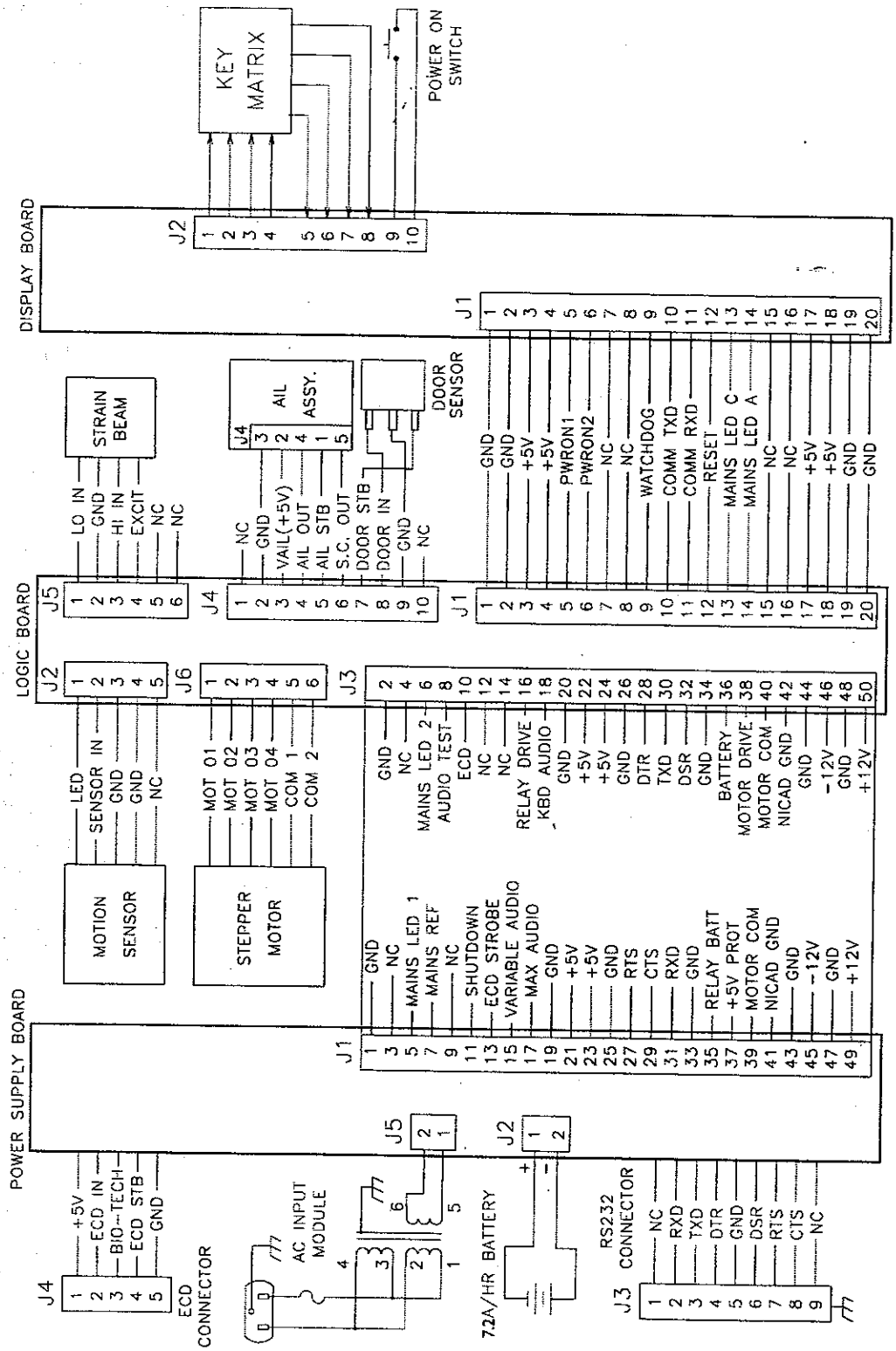


Figure 4-4. PC-1 Pump/Controller Interconnect Diagram

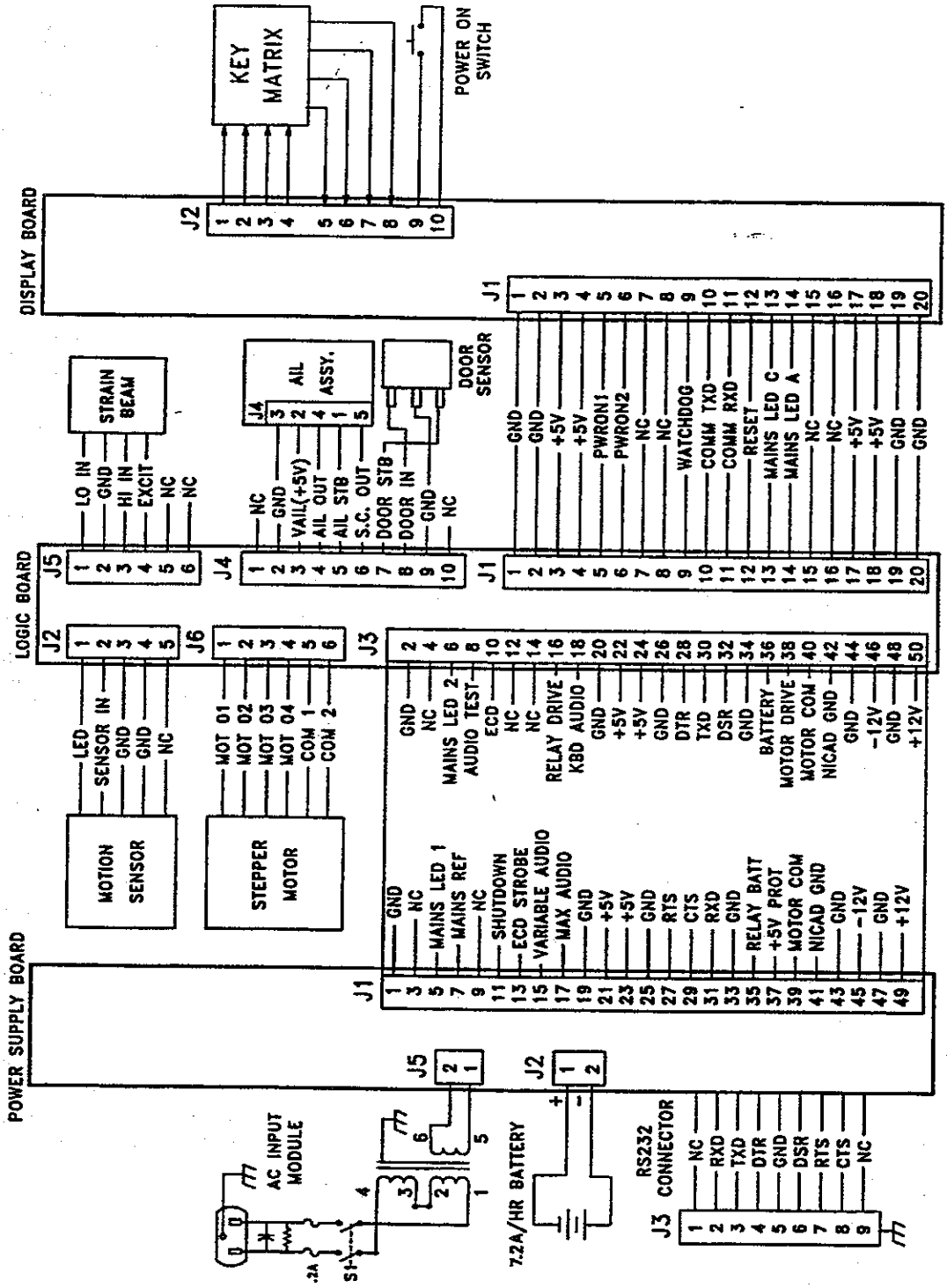


Figure 4-4a. PC-1 Pump/Controller (220V) Interconnect Diagram

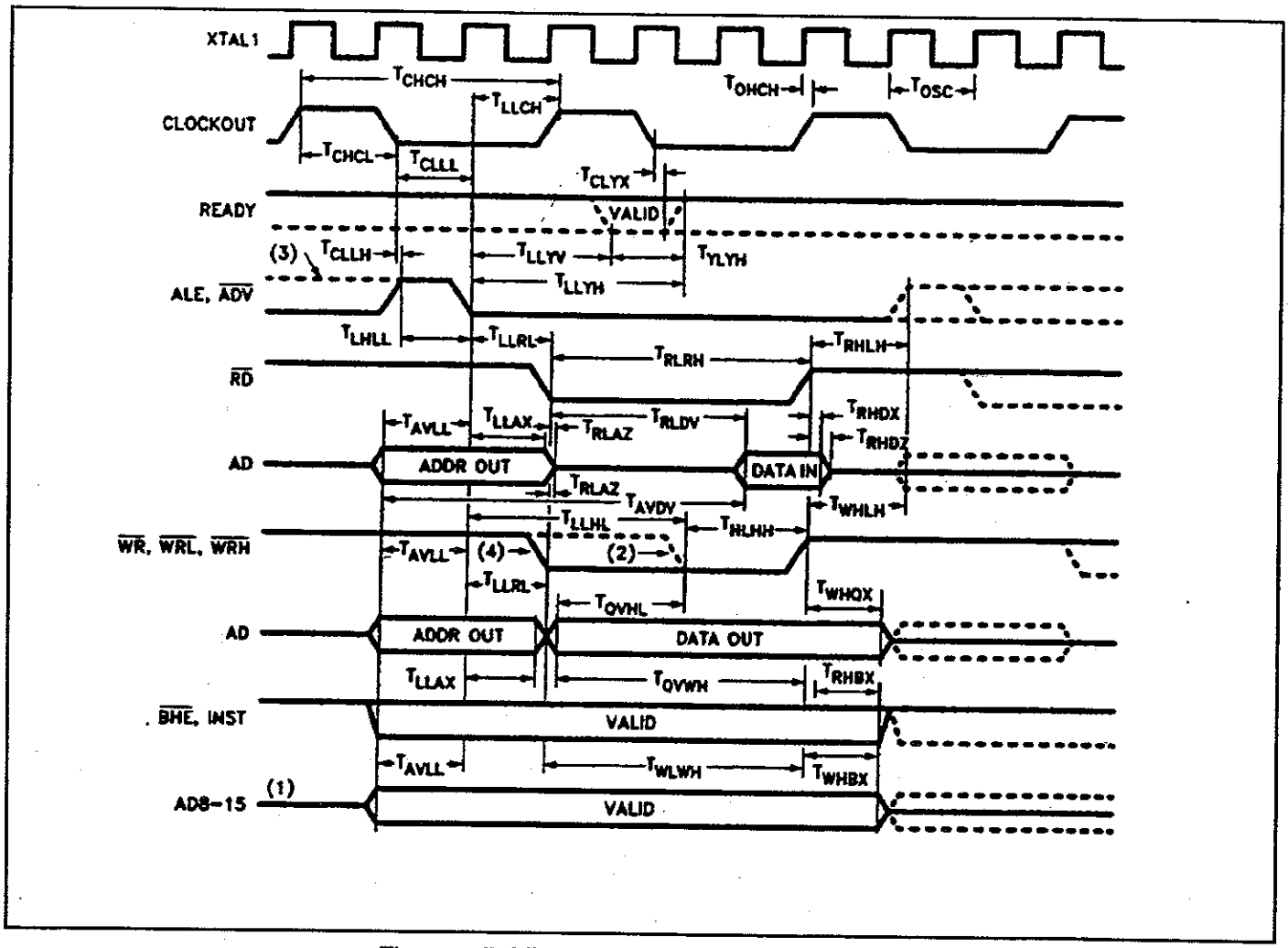


Figure 4-5. Microprocessor Timing Waveforms

the instrument's operating code; a non-volatile memory for retention of programmed infusion parameters, error log storage and general system use; a logic decoder to define memory space, implement ready logic, decode sensor strobes and controls audio. The interaction of the logic subsystem components and instrument hardware is functionally depicted in the Logic Block diagram, Figure 4-2 or 4-2a. The electrical interconnection of the instrument's components is shown in Figure 4-4 (110V) and 4-4a (220V).

The 80C196KB's architecture implementation uses a linear non-segmented address scheme, i.e., data memory, program memory and I/O share the same address space. The maximum address range is 64K bytes and since the program is larger than 64K, a bank switching scheme is implemented in the EPLD with four 64K banks. Since data, code and I/O must share the address space, not all of the ROM will be utilized.

4.3.2 Functional Operation

Integer/Fractional Keypad Instruments
A 11.0592 MHz crystal external to the microcontroller provides the master clock signal. The microprocessor timing waveforms are shown in Figure 4-5.

Titration Keypad Instruments
A 12 MHz crystal external to the microcontroller provides the master clock signal. The microprocessor timing waveforms are shown in Figure 4-5.